#### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO WAVE 1

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

## RULE 26 EXPERT REPORT OF JOHN MIKLOS, M.D. TVT-SECUR

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure.

#### I. QUALIFICATIONS

I received my BS in Biology from Juniata College in Huntingdon, Pennsylvania in 1982 and graduated with a MS in Physiology and a MD degree from the Medical University of South Carolina School of Medicine, in Charleston, South Carolina in 1985 and 1989, respectively. I did my residency training in Obstetrics and Gynecology at Hahnemann University Hospital in Philadelphia, Pennsylvania between 1989-1993. Then I completed my first two-year fellowship at Good Samaritan Hospital in Cincinnati, Ohio in Urogynecology & Reconstructive Pelvic Surgery in 1995. I went on to complete a second fellowship in minimally invasive reconstructive pelvic surgery at Atlanta Laparoscopic Training Center in Atlanta, Georgia in 1997. I was appointed and served as the Director of Urogyencology and Reconstructive Pelvic Surgery at Georgia Baptist Medical Center (1995-1997). I was a clinical instructor at the Advanced Laparoscopy Training Center, Marietta, Georgia (1995-1999) and at the Medical

College of Georgia in Augusta (1996-1999). I became the Director of Urogynecology for the Atlanta Urogynecology Associates (1997-2014) as well as the International Urogynecology Associates offices in Beverly Hills, CA and Atlanta, Georgia (2012-2014). I have recently been awarded the title of full adjuvant Professor in Obstetrics & Gynecology specializing in Urogynecology at Emory University in Atlanta, Georgia. I have been in a practice exclusively dedicated to female pelvic floor disease and its surgical correction for 18 years. My partner, Robert D. Moore, D.O., and I often operate together as a team. During this time, my partner and I have operated on approximately 8,000 patients from 50 states and 52 countries.

I received and maintain my Board Certifications in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. I am a Fellow in good standing of: American College of Obstetrics and Gynecology (FACOG), American College of Surgeons (FACS), and a member of: American Association of Gynecologic Laparoscopy (AAGL), American Urogynecology Society (AUGS), American Urologic Association (AUA) and Society of Gynecologic Surgeons (SGS).

I have been a member of the American Urogynecology Society since 1993 and have served on the Board of Directors and taught postgraduate courses at the combined International Urogynecology Association (IUGA) and American Urogynecology Society (AUGS) Meetings including: Laparoscopic vaginal reconstructive vaginal surgery and the surgical treatment of mesh complications after vaginal mesh reconstructive surgery. I have also been a member of the American Association of Gynecologic Laparoscopic Surgeons (AAGL) since 1992 and have served on the AAGL Board of Advisors (2008-2010) and the Urogynecology Special Interest Group (2010-2014). In 2014 I was nominated as one of two candidates for a position as an AAGL trustee.

I was nominated for Association of Professors of Gynecology and Obstetrics (APGO) "Excellence in Training" Award in 1992 and received the APGO Award in 1997. I have been given various surgical and scientific awards including: AAGL - Jerome Hoffman Prize Paper Award (2000), AAGL - Kurt Semm Award for Excellence in Pelviscopy (2007), AAGL - Annual Golden Laparoscope Award (2000 and 2014).

I have been a journal reviewer for Obstetrics and Gynecology, International Urogynecology Journal and Pelvic Floor Dysfunction, Journal of Female Pelvic Medicine, Journal of Minimally Invasive Gynecologic Surgery and the American Journal of Obstetrics and Gynecology. I have published in the majority of the above mentioned journals and also in the following: Journal Sexual Medicine, The Female Patient, Journal of Pelvic Surgery, Urology, Mayo Clinic Proceedings, Current Opinions Obstetrics & Gynecology, and the Journal of Reproductive Medicine.

I have written nearly 100 peer-reviewed publications and 30 book chapters and one textbook with more than 25 papers and 9 book chapters specific to synthetic or allogenic grafts. (Please see Curriculum Vitae attached as Exhibit A.) I have authored or coauthored approximately 150 scientific abstracts and have performed surgery and given surgical lectures in more than 20 countries.

My first experience with mesh used to treat pelvic floor defects was in 1998, when I was trained on the Johnson & Johnson/Gynecare TVT sling for the treatment of stress urinary incontinence in Uppsala, Sweden. After returning to the United States, 5 other surgeons and I were among the first to implant the TVT retropubic synthetic sling. I became an advisor and preceptor on the procedure until approximately 2002. I estimate I taught more than 400 surgeons in my operating room on how to implant the TVT sling.

During the early 2000s until approximately 2009 I was using Gynemesh PS for laparoscopic sacrocolpopexies and as well as for some posterior vaginal wall augmentation during posterior repairs. In approximately 2003, I was approached by Gynecare/Johnson & Johnson and asked if I would go to France to evaluate the Transvaginal Mesh technique and, if I accepted, the company wanted me to sign an agreement guaranteeing my commitment to use the product. I explained that I would not sign a commitment to a surgical technique that I had not evaluated or even seen. Gynecare made a decision to sponsor my trip to France without my guaranteed commitment.

I went to France to meet Dr. Michele Cosson and Dr. Bernard Jacquetin and to evaluate TVM for pelvic organ prolapse in the operating room as well as in a laboratory setting. I expressed my opinions about both the pros and cons of this investigative new surgical technique to Gynecare and explained that I felt it was too dangerous to perform and to teach to other surgeons.

I was also asked by Ethicon Gynecare to travel to Belgium to meet with Dr. Jean De Leval to evaluate his new anti-incontinence technique known as the TVT-O but due to my schedule I declined the invitation. Several weeks later I attended a cadaveric training course on the same technique in Somerville, NJ. I discussed the pros and cons of this new technique with the Gynecare representatives during my visit. Several weeks later, Brian Luscomb of Gynecare came to observe my implantation of the TVT-O on a patient of mine. There were no complications but I made a decision not to use the product again.

In 2006 Gynecare, invited me to attend a cadaveric training session in Orlando, Florida on the single incision sling known as TVT-Secur. The course"s primary instructor, Dr. Vincent Lucente, was also a key opinion leader for Gynecare. During the cadaveric training session I

discussed the shortcomings of the TVT-Secur device including: 1) razor blade insertion device and its extremely sharp nature 2) the poor releasing mechanism of the mesh sling from the insertion blade 3) the lack of conformity to dissection technique as discussed during a preceding lecture (I recommended putting one's finger into the incision to touch the ischiopubic rami to determine adequate insertion width and depth for mesh placement) and finally 4) the absolute necessity of performing a cystourethroscopy after the operation to assure patient safety.

Afterwards Dr. Lucente invited me to do a scientific study with him on the safety and efficacy of the TVT – Secur. I performed the TVT-Secur on 28 patients, and combined the intraoperative and postoperative data with Dr. Lucente's 77 patients. Our immediate post operative results revealed a dismal 71 % cure rate at 6 weeks. My overall cure rate at 6 weeks was 79% (22/28) and Dr. Lucente's cure rate using TVT-Secur was 68.8% (53/77). As a result, I felt I could no longer support the Gynecare TVT-Secur sling as an option for stress urinary incontinence and ceased use of the product.

In 2002-2003 I was contacted by US Surgical to be a medical advisor and one of the first surgeons in the country to perform a new innovative surgical procedure known as the Posterior IVS Tunneller. This procedure was utilized to treat posterior vaginal wall defects (rectoceles) and vaginal vault prolapse. After performing less than 10 cases and after reviewing the results from American and Australian surgeons, I abandoned its use due to high mesh extrusion rates, abscesses and persistent sinus tract formation.

From 2005-2008 Dr. Moore and I continued to use Gynemesh PS (Gynecare) and AMS polypropylene mesh for laparoscopic sacrocolpopexy and wrote the largest single center study on laparoscopic sacrocolpopexies mesh complications:

Risk of mesh extrusion and other mesh-related complications after laparoscopic sacrocolpopexy with or without concurrent laparoscopic-assisted vaginal hysterectomy:

experience of 402 patients. Stepanian AA, Miklos JR, Moore RD, Mattox TF. J Minim Invasive Gynecol. 2008 Mar-Apr 15(2);186-96.

In this study 402 laparoscopic sacrocolpopexies were done over approximately 3.5 years. Our analysis, with a mean follow-up of 12 months, revealed the following complication: 1.1% dyspareunia, 0.2% infection rate, 0 erosion rate, and 1.2% vaginal extrusion rate. Dr. Moore and I have now performed more than 1600 laparoscopic sacrocolpopexies since 1998.

Dr. Moore and I currently perform approximately 450 surgeries annually for pelvic floor reconstruction. Over the last 4 years we have removed more than 500 pieces of mesh from patients suffering from complications. We presented 3 abstracts at the 2014 combined American Urogynecology Society and International Urogynecology Society Meeting:

- 1) Miklos JR, Chinthakanan O, Moore RD, et al. The IUGA/ICS Classification of synthetic mesh complications in female pelvic floor surgery: A multicenter study, AUGS/IUGA Scientific Meeting Washington, DC July 2014
- 2) Chinthakanan O, Miklos JR, Moore RD, et al. Mesh removal following sling/mesh placement: a multicenter study AUGS/IUGA Scientific Meeting Washington, DC July 2014
- 3) Chinthakanan O, Miklos JR, Moore RD, et al., Indications and surgical treatment of midurethral slings complications: a multicenter study, AUGS/IUGA Scientific Meeting Washington, DC July 2014

These three studies are the largest known studies on mesh complications and female reconstructive surgery. (At the AUGS/IUGA meeting, I was one of three faculty members to teach the postgraduate course on Pelvic Mesh Complications: Treatment and Surgery). The first of these three abstracts: *The IUGA/ICS Classification of synthetic mesh complications in female pelvic floor surgery: A multicenter study*, has been accepted for publication in the International Urogynecology Journal (2016). This is the largest published manuscript on the subject of mesh complications and female urogenital surgery. Since the evolution of transvaginal slings and mesh procedures Dr. Moore and I have explanted more than 700 mesh devices, with more than 500 since 2010, including: Gynecare Prolift, Prolift +M, Prosima, TVT retropubic, TVT-O, and TVT – Secur slings. In our multicenter study on

mesh removal noted above, we removed midurethral synthetic slings in 83.3% (373/445) of those presenting with symptomatic mesh complications. A number of the midurethral slings removed were TVT-Secur slings.

I have reviewed numerous Instructions for Use (IFU) for a variety of medical products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the devices.

I have extensive clinical experience with IFUs and instructing patients about the adverse events and risks contained in IFUs. I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs and consenting patients regarding IFUs.

I have significant experience with pelvic repair surgery of all types with and without biologic or synthetic augmentation materials (i.e., grafts). I have multiple approaches to pelvic reconstructive vaginal surgery including transvaginal, abdominal, and laparoscopic and am considered well versed enough to lecture nationally and internationally.

I am familiar with the TVT-Secur specifically, as opposed to just mesh products and slings generally, as I have attended lectures, seen videos, read scientific articles and medical clinical trials, and reviewed the instructional and physician training materials for the TVT-Secur. I have personally been involved with a TVT-Secur study which proved to me that the device is an inferior product in terms of efficacy for stress urinary incontinence. I have personally removed a number of TVT-Securs with the most recent removal in the last 6 months. I know this because of our data collection needed to present the three scientific abstracts mentioned above.

#### II. EXPERT OPINIONS

All of my opinions in this report I hold to a reasonable degree of medical or scientific certainty.

#### Studies showed that the risks of TVT-S were greater than its benefits

Doctors who utilize products in their patients, and particularly products that will be permanently implanted in their patients" bodies, reasonably expect that the device"s manufacturer will have taken into account all potential risks and weigh those risks against any benefits that the design of the product may provide. A reasonable medical device manufacturer will consider not only the risks associated with its device, but how those risks may be expected to affect the patient: how long they may last, how serious they may be, and whether and how the complication can be treated. If the problems that are known or reasonably may be expected to be associated with a particular design can cause problems that are serious, chronic or permanent, or that can be difficult or impossible to treat and resolve, no reasonable manufacturer would provide that device for permanent human implantation unless the benefits so far outweigh those risks that it could be justified.

Stress urinary incontinence ("SUI"), the condition that TVT-S was sold to treat, is not a life-threatening condition. While SUI may be uncomfortable and embarrassing, it is not painful or dangerous to the patient"s health. Particularly when there were a number of other more or equally effective alternative surgeries and products available to treat this non-life threatening disorder, the risks inherent in the TVT-S design outweighed any claimed benefit.

Published medical literature and Ethicon"s internal documents reflect the inadequate efficacy and safety of the TVT-S. For example, Ethicon"s documents reflect "high "failure" rates

across multiple centers" with TVT-S in 2007.<sup>1</sup> A study published in 2010 showed a 42% failure rate, and concluded that "Our experience shows that despite its good short-term efficacy, TVT-Secur is associated with a high recurrence rate of SUI. Therefore, TVT-Secur does not seem appropriate for SUI first-line management in women." Gynecare's own internal document states "... the TVT-Secur product is associated with inferior patient-reported and objective cure rates at 1 year, and higher reoperation rates when compared to standard mid-urethral sling (e.g. TVT/TVT-O) ..." (ETH.MESH.05600922)

A January 22, 2007 internal e-mail reflects that 49 TVT-S complaints were reported to Ethicon from Germany in or before December 2006, including bleeding and hematomas, and further indicates that "most state "failure incontinence after several weeks"."

On October 22, 2007, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a recommendation regarding single-incision slings, like the TVT-S, stating that ",Current evidence on single -incision suburethral short tape insertion for stress urinary incontinence in women is limited in quality and quantity. Therefore this procedure should be carried out only in the context of controlled clinical trials with adequate duration of follow-up (for example, a minimum of 2 years)." An Ethicon employee summarized the NICE recommendation, stating "the reasons are limited clinical data (study design and quality, # of patients, limited length of follow-up) and the uncertainty expressed by the specialist advisers on the safety as well as the efficacy profile." Another Ethicon employee responded, "I wonder why we have attracted such unusually harsh judgment (in draft). Is it another echo of our launching with less than gold-standard clinical data do you think?" Ethicon launched TVT-Secur without any long-term clinical data (ETH.MESH.00134795) despite "worries" by KOLs" Nilsson and Artibani and Ethicon's European Marketing Manager, Harel Gadot.

(ETH.MESH.03172197) In fact, Ethicon board members had put in place an accelerated launch on the the product, and performing a clinical study would have caused a delay in the launch of the TVT-Secur. (Deposition of Patricia Hojnoski April 16, 2013 Page 100 Line 15 to Page 111 line 9)

On October 25, 2007, Dr. Aran Maree, Ethicon"s Medical Director for Australia and New Zealand, attributed the failures to the product having been "launched as a substitute for TVT without enough clinical data to justify the roll-out," and that the TVT-S training program did not result in "competency in device insertion." On November 2, 2007, Dr. Maree advised Catherine V. Beach, Worldwide Vice-President of Quality Assurance, that three seasoned surgeons experienced multiple 6-week failure rates-this included Prof. Malcolm Frazer, a surgeon who had performed about 700 TVT cases over the years, who experienced 13 failures out of 20 surgeries (a 65% failure rate). The two other surgeons from Australia mentioned in Dr. Aran Maree"s email, Dr Bruce Farnsworth and Prof. Marcus Carey, had approximately 30% and 40% failure rates respectively at 6 weeks post operatively. (ETH.MESH.00827141These surgeons reported that their failure rates with the TVT-S were significantly higher than those experienced with the TVT or TVT-O.

In late October 2007, Dr. Maree instituted a "quality block" on the TVT-S in Australia and New Zealand, which prohibited the product from being released. Dr. Maree met on October 31, 2007 with Ethicon Medical Director David Robinson to "review with...Ethicon, the Australian and international postmarket surveillance results for [TVT-S]." It was agreed in this meeting that the adverse outcomes reported in Australia were consistent with outcomes experienced elsewhere. It was determined that "there was currently little significant surgical benefit in using SECUR over other existing procedures" and the decision was made to withdraw

the product from the Australian and New Zealand markets until further "high quality objective data" becomes available confirming optimal technique and enhancing product efficacy." A Senior Product Manager in Australia explained that surgeons did not wish to be retrained on the TVT-S due to (1) lack of clinical evidence, (2) steep learning curve and surgeons are not prepared to risk their patients, and (3) IFU versus "nuances" are very different, and (4) current data suggests success rates of 65-70%, which was significantly lower than other available treatments. By December 10, 2007, Australia had issued a "complete block" on the TVT-S. 14

In an April 24, 2008 internal e-mail regarding comments attributed to Dr. Vincent Lucente, an Ethicon preceptor and "Key Opinion Leader," an Ethicon employee stated that "[w]hen [Dr. Lucente] went through his presentations with me he was quite scathing of...TVT Secur as having problems and being behind MINI ARC in terms of reliability. I do know that several comments were made in surge[r]y (off camera) about TVT Secur..."

In a June 18, 2008 internal memorandum regarding communications with Key Opinion Leader physician Carl Nilsson relating to TVT-S, it was noted that the physician consultants advised that "[t]here is no documentation that Mini-Sling is safer and with equal efficacy as TVT." <sup>16</sup>Published clinical data also demonstrates the lack of efficacy of the TVT-S device. Ethicon"s Medical Director, Piet Hinoul, and other surgeons, enrolled 194 subjects randomized to TVT-O versus TVT Secur. <sup>17</sup> One year follow-up outcomes were obtained for 85 TVT-O and for 75 TVT-Secur patients. Subjective reporting of SUI at one year was lower in the TVT-O group (8%) compared to TVT-Secur (24%) (p<0.05). The odds ratio (OR) for repeat incontinence surgery at one year was significantly greater for TVT-Secur (OR 2.3, 95% CI 1.9 to 2.7). Incontinence QOL was significantly better in the TVT-O group.

A Cochrane Review analyzed various single-incision devices used for urinary incontinence in women by interpreting the results of a number of reported studies and trials. Although Ethicon had already withdrawn the TVT-S from the market at the time of the Cochrane report, the report included the TVT Secur "so that level 1a data" would be "available in the literature to confirm its lack of efficacy." 18 Most of the review's findings were derived from studies involving TVT-Secur. The report noted that single-incision slings resulted in higher incontinence rates when compared with inside-out transobturator slings (30% vs 11 %; RR 2.55, 95% CI 1.93 to 3.36). The adverse event profile for single-incision slings was also noted to be substantially worse, and involved higher rates of vaginal mesh exposure, bladder/urethral erosion, and operative blood loss. Perhaps most significantly, overall results showed that the TVT-S was "considerably inferior to retropubic and inside-out trans obturator slings." The authors of the study concluded that "TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use." Other studies have similarly concluded that the TVT-S has inferior efficacy when compared with other SUI devices. 19

Ultimately, after the FDA issued a 522 order for the TVT-S in January 2012 requiring clinical studies to demonstrate the safety and efficacy of the device, Ethicon withdrew the TVT-S from the market.

As a physician who has regularly used various medical devices to treat stress urinary incontinence, and who has worked with medical device manufacturers in conducting clinical studies and in evaluating SUI treatment devices before and after marketing, it is my opinion that Ethicon failed to adequately test the TVT-S design before marketing the device for implantation into women. A properly-conducted clinical study conducted prior to marketing the TVT-S

would have demonstrated to Ethicon that the TVT-S was not as effective as available alternative treatments and devices, and created the potential for unreasonable risks.

Ethicon never had any data, clinically or otherwise, to support the use of the TVT-S device. To the contrary, all of the information available to Ethicon demonstrated that the efficacy of the device could not be established. In light of the lack of proof of efficacy, the significant risks or increased risks associated with the device outweighed any possible benefits and rendered the product unreasonably dangerous.

#### **Design Flaws of TVT-Secur**

Although my understanding is that Ethicon utilized the TVT and TVT-O as predicate devices in its 510(k) application to the FDA, these devices are completely different from the TVT-Secur.

In fact, a key opinion leader from Australia, Prof. Malcolm Frazer, said that TVT-Secur is so "utterly different to the other TVTs that it probably shouldn"t be called a TVT"<sup>20</sup>. For example, the inserters used in the TVT-Secur had never been used before and the length of the tape were markedly different and made the TVT-S more prone to fail, as the angle of correction at the urethra was often not maintained<sup>21</sup>. The sharp edges of the TVT-S insertion device tear tissue upon implantation and removal, which can cause or contribute to complications, including pain, inflammation, and erosion.<sup>22</sup>

The TVT-S insertion method and design often caused the anchoring to dislodge, difficultly in properly tensioning the mesh, difficulty in removal of the insertion device after fixation, and lower success rates than other available SUI products.<sup>23</sup> In 2007, Ethicon"s Quality Board conducted an analysis of the TVT-S in response to product-related complaints in Australia, which revealed that implant pull-outs with the inserter and difficulty in removing the

inserter were the two most significant complaints in the United States.<sup>24</sup> In fact, this was such an issue that key opinion leader and preceptor Dr. Vince Lucente recommended a technique not described in the TVT-Secur IFU: "Dr. Lucente has also found the placement of a very narrow malleable retractor (such as those used in ENT surgery) between the mesh and the inserter to be helpful in creating stability for the mesh while removing the inserter."

(ETH.MESH.07396540)

In an August 19, 2007 internal PowerPoint presentation, an Ethicon marketing manager identified the following complications with the TVT-S: (1) insertion difficulties; (2) releasing difficulties; (3) fixation tips not staying in place; (4) bladder perforations; (5) excessive bleeding; (6) failures – tensioning.<sup>25</sup>

The design flaws listed above will cause pain, tissue damage, inflammation, and the mesh will shift and move, curl and scar in asymmetrically, and become too tight.

Particularly because there was no evidence to indicate or demonstrate that this device was as or more effective than alternative treatments, the significant potential for the severe and permanent risks or increased risks associated with the TVT-S design, as set forth above, outweighed any alleged benefits and made the device not reasonably safe.

#### Failure to warn/inadequate instructions

As an active explanting surgeon for this particular transvaginal mesh, I have reviewed and am familiar with the Instructions for Use (IFU), Physician Training materials, and sales and marketing materials prepared by Ethicon for the TVT-S. I have also reviewed the IFUs for many other medical products that I have implanted and explanted in patients during the last 17 years I have been practicing urogynecology and pelvic reconstructive surgery.

Along with other information that is provided by the device manufacturer in promoting products and training physicians to use those products, physicians must be able to reasonably rely upon the product IFU to make informed decisions about whether and how to use a medical device. Relying on the IFU, for surgical technique, increases consistency between surgeons" technique and thus efficacy and complication rates. Gynecare"s Medical Director, David Robinson MD, touted the importance of specifically following the TVT-Secur IFU in an attempt to shorten the learning curve. (ETH.MESH.03922618). Failure to communicate a consistent "best" technique can result in non-reproducible efficacy results and varying rates of complications. This was an ongoing problem for Gynecare as the TVT-Secur technique was variable (i.e. U versus Hammock) as well as markedly different. Internal documents suggest the TVT-Secur should have been launched as two separate products due to the two different approaches recommended in the IFU as "this would have reduced the misuse, confusion and reduced the learning curve" (ETH.MESH.09951087). The contents of the IFU should also assist and help the doctors analyze all of the potential risks that are associated with a product to be able to properly consider whether a particular product is an appropriate surgical option for a given patient.

Physicians also rely on information provided by medical device manufacturers in other forms besides the IFU, such as patient brochures, physician training materials, and direct communications with sales and marketing personnel and other company employees. In order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device seller to provide all pertinent information known to the company that could impact a reasonable physician selection to use that product. However, the TVT-Secur technique was consistently changing and not shared uniformly among

the surgeons and Gynecare sales representatives. (ETH.MESH.07396540)

(ETH.MESH.01784435) Not only were the educational materials not updated or consistent but some Ethicon employees felt that using a preceptor was the best form of training (ETH.MESH.03921637), as this increases quality assurance. Internal documents revealed a lack of conformity in training and not all surgeons were trained by a physician preceptor but instead by CD, "watched a link-up" or a sales representative. (ETH.MESH.03921638) This "less then perfect surgeon training" was specifically noted by Mark Yale, Gynecare"s Director of World Wide Risk Management. (ETH.MESH.00330141). The failure in the consistency of training is obvious and the results were detrimental in terms of patient safety and efficacy. Failure to provide physicians with relevant information bearing on the potential safety and efficacy of a product that is known to the manufacturer prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to permanent implantation of the medical device.

#### Ethicon's TVT-S physician training was inadequate and improper

While the TVT-Secur should never have been sold given the defective design of the device, in my opinion the TVT-S required greater specialized training than previous generations of TVT devices. The TVT-S involved a new and difficult insertion technique that was not similar to other Ethicon products or other competing SUI slings available on the market. Introduction of a novel product/surgery requires the manufacturer to ensure proper training and instruction for physicians who will be utilizing the new device.

Dr. Ramy Mahmoud, Ethicon's Worldwide Vice President for Evidence Based Medicine and former Chief Medical Officer at Ethicon, testified that he recalled discussing with Ethicon's

Medical Director David Robinson and other surgeons the importance of proper technique in implanting the TVT-S and "how important the training was in order to adopt the correct technique in order to achieve the desired success rate." Dr Maree testified that the TVT-Secur was a product that had either a substantially new technique or was significantly modified from the predecessor products (TVT and TVT-O) (Deposition of Aran Maree 7.22.13 page 137 line 8-16). Dr Maree also testified that Dr Frazer, an Australian KOL, also thought the device was a substantially new technique and a different product. (Deposition of Aran Maree 7.22.13 page 137 line 18-20 and page 139 line 2-7). It is my opinion that due to its novel technology, unproven efficacy and non reproducible technique, Ethicon should have, but failed to provide adequate and follow-up training.

Ethicon's documents reflect that early clinical experience demonstrated that the learning curve for TVT-S was longer than anticipated, particularly due to the unique mesh tensioning technique.<sup>27</sup> In an internal memo, Ethicon engineer and TVT-S co-inventor Daniel Smith identified the "implications" of achieving competency on the TVT-S: "extensive training requirements, possible loss of market share." As Mr. Smith noted: "Do not underestimate the learning curve for a device which seems simple." Dr. Vincent Lucente, an Ethicon consultant and preceptor, reported a 40% failure rate in his first 25 patients, and 30% of his first 77 patients. This is thicon's Dr. Maree noted in an October 30, 2007 e-mail that given Dr. Lucente's reported failure rates it was "not at all surprising that we may have similar or higher failure rates here." Another of Ethicon's physician advisors and Key Opinion Leaders, Carl Nilsson, advised the company in June of 2008 that his learning curve for the TVT-Secur was "100 patients before he was very good with very dry results." Dr. TC Khoo, Ethicon's Vice

"related to operator based technique deployment." Dr. Khoo recognized the important of addressing physician training issues and the need "to eliminate any possibility of product related issues while considering the adequacy of training and what is needed to properly rollout a device" so that patients do not get "the short end of the stick," and stated that the "responsibility of controlling the adequacy of training is critical." <sup>34</sup>

Ethicon"s European Medical Director, Axel Arnaud, observed that Ethicon could not "ignore that some surgeons who have been able in the past to successfully perform TVT and TVT-O are now struggling to achieve the same results with Secur," and stated that he wished "the solution would just be to tell them to go back to their homework, but I am not sure it is the best one." Ethicon"s Medical Director Dr. David Robinson responded that "[i]t is just as clear that we are having some type of training problems and in order to prevent wide spread negative talk, I think we must take palliative steps quickly." Despite this internal communication and information known or available to the company, no action was taken to revise the TVT-S training.

In an October 25, 2007 correspondence, Dr. Maree expressed his concern that the "current [TVT-S] training program may not result in competency in device insertion or result in clinical efficacy. There appear to be "tricks" to insertion of the product and removal of the inserters which prevent dislodging the device in the process." Dr. Maree stated that "the average practitioner finds it too complicated to insert correctly and cannot master the process," and due to surgeon"s inability to achieve competency in inserting the product, recommended "restrict[ing] access to those who can."

Despite the information known or available regarding the importance of thorough training and the difficulty in the TVT-S procedure, Ethicon did not limit the sale or marketing of

the TVT-S to only experienced and trained physicians. To the contrary, Ethicon often relied on engineers and sales personnel to "train" physicians on the implantation of the TVT-S device.<sup>39</sup> In fact, to address TVT-S training concerns, Ethicon"s Quality Board in 2007 recommended that the company "keep [the TVT-S] product in market to train people."<sup>40</sup>

Additionally, in making an informed decision of whether or not to use a permanent medical implant, the physician must be warned not only of the true difficulty of the procedure. but also the potential adverse events that may be associated with the product, including the frequency, severity, duration and potential permanence of those adverse events. If a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to the people who will be using its products or having those products implanted in their bodies. This concept is reflected in internal Ethicon communications from Meng Chen, Ethicon's Associate Medical Director for Worldwide Quality, wherein she urged the company to change the IFU for TVT-S because "[o]ur post-market knowledge with these products are much more than what we have in the IFUS of all three types of TVTs,"41 and also expressed concern that any reference in the TVT-S IFU to certain identified complications as "transitory" (or temporary) is inadequate, and stating that "from what I see each day, these patient experiences are not "transitory" at all." As Ms. Chen explained to Ethicon's upper management, "One of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflect[s] the current knowledge of the manufacturer's on the potential adverse reactions."43

It is my opinion that certain statements in the TVT-S IFU are false and misleading because they contradict information known or at least available to Ethicon, according to Ethicon's own documents.

The IFU states that "[a]nimal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient...." Contrary to this statement, however, Ethicon"s documents reflect that the polypropylene material used in the TVT-S device causes an "excessive" and "chronic" foreign body reaction and "intense" and "chronic" inflammation.<sup>44</sup>

The information provided to physicians and patients for the TVT-S device, including the IFU and promotional materials, did not properly warn about the risks associated with the TVT-S. Even for risks that were disclosed, the IFU and other materials provided by Ethicon did not adequately convey the frequency, severity and duration of the risks that were disclosed.

There were numerous serious safety risks associated with the TVT-S that were not included in the TVT-S IFU, including but not limited to: chronic or permanent pain; voiding dysfunction; dysuria; abscess formation; painful intercourse that may not resolve; neuromuscular damage; leg pain; recurrence (of incontinence); significant bleeding (including hemorrhage or hematoma); one or more revision surgeries may be necessary to treat adverse reactions; the mesh is a permanent implant and significant dissection may be required if the mesh needs to be removed; urge incontinence; urinary frequency; urinary retention; adhesion formation; atypical vaginal discharge; or that exposed mesh may cause discomfort to a sexual partner during intercourse.<sup>45</sup>

There was never any warning provided that the polypropylene material used in the TVT-S mesh causes intense, chronic and excessive inflammation and foreign body reaction. Ethicon failed to warn that the inflammatory response to the TVT-S mesh material was directly correlated to shrinkage and pain. 46

Ethicon"s internal documents reflect that the contraction/shrinkage rate associated with its pelvic repair mesh products was as high as 20% to 40% (or higher), and that this contracture was associated with deformation of the mesh which can cause pain.<sup>47</sup> However, no warning was ever provided about the frequency, permanency or severity of this increased risk.

Ethicon never provided any warning of the risks of nerve damage, nerve entrapment, nerve tethering or nerve severing caused by the TVT-S mesh after implantation.<sup>48</sup>

Ethicon did not adequately warn that the sharp insertion device created the risk of nerve damage and tissue injury upon implantation.

Ethicon failed to warn about the potential for vaginal deformation caused by the mesh.

Ethicon failed to warn that the safety and efficacy TVT-S had never been evaluated in clinical trials prior to being marketed.

Ethicon failed to provide any warning that the clinical data available to the company showed lower efficacy rates and higher complication rates when compared with alternative available devices and treatments for stress urinary incontinence.

Ethicon provided no warning of injury due to the device remaining attached to the inserter after implantation.

Ethicon failed to warn about the difficulty of removing the TVT-S mesh in its entirety once it is implanted.

Ethicon failed to provide any instruction or direction as to how to address complications, or what to do in the event mesh removal was necessary. In fact, before the TVT-S was sold, Ethicon's internal documents reflect concern that providing instruction or direction regarding removal of their mesh would cause physicians to worry that mesh removal could be necessary, and indicate concern that "overinformation" about mesh removal would be "digging my own

grave."<sup>49</sup> Doctors expect a reasonable medical device manufacturer to warn them about all potential risks known to be associated with its product, regardless of how that may affect their attitudes towards the product.

Ethicon did not provide any warning to physicians or patients that the surgical procedures necessary to remove mesh can themselves cause serious, long-term complications.

Having read and relied upon IFUs for urogynecologic medical implants over the past 17 years, it is my opinion that the type of information detailed above should be communicated to surgeons so that they can make safe treatment choices for their patients. Even if Ethicon did not have knowledge of the information at the time of the products" launch, once this information became available, the company should have made changes to the IFU and otherwise made reasonable efforts to ensure that physicians continue to have the information necessary to make informed and safe treatment decisions for patients. If physicians are not fully and timely informed of all of the information known to the manufacturer bearing on the safety and efficacy of the product, they cannot be expected to perform an adequate risk-benefit analysis or obtain adequate informed consent from their patients.

Doctors not only must rely on the manufacturer to provide adequate warnings about the products risks, but also to provide adequate instruction on how to safely use the product so as to avoid unnecessary risks. The documents that I have reviewed indicate serious inadequacies in the instructions for implantation of the TVT-S, which created even greater potential for complications. In December 2006, Ethicon"s European Medical Director, Axel Arnaud, reported to Daniel Smith (Ethicon engineer and co-inventor of the TVT-S) and Dr. David Robinson (Ethicon"s Medical Director) that surgeons, even Key Opinion Leaders "who have been correctly trained and who have passed the learning phase, are raising concerns about the efficacy of the

TVT Secur.... They are asking for clear recommendations about the way to perform the procedure, in particular about the size of the dissection, the tension to be given to the tape and the way to perform a cough test." No such instructions were in the initial TVT-S IFU, and no such instructions were ever provided for the TVT-S.

An Ethicon marketing manager identified several technique-related complications with the TVT-S in an August 19, 2007 internal PowerPoint presentation, including: (1) insertion difficulties; (2) releasing difficulties; (3) fixation tips not staying in place;... (5) excessive bleeding; (6) failures – tensioning.<sup>51</sup> The IFU vaguely and generally references bleeding, and "overcorrection" and "undercorrection," but fails to offer any other information about these risks, the extent or severity of these risks, or how to minimize or avoid these risks.

Ethicon's Australian and New Zealand Medical Director Dr. Aran Maree similarly reported that Ethicon Key Opinion Leaders had advised that "the [TVT-S] IFU is fundamentally misleading" because "tension-free, tension-less and placement with no tension are complete misnomers." On November 2, 2007, Dr. Maree noted that "It is my understanding that some suggestions had come out in the form of (i) increased tension required with this mesh with "pillowing of peri-urethral tissues required", (which is quite the opposite of TVT-O recommendations), as well as (ii) new tips for minimal dissection when introducing the product. We also discussed the fact that at this time some or all of these suggested changes may not be incorporated into the [IFU] or technical training material." Despite this information known or available to Ethicon, no such information was included in or added to the TVT-S IFU at any time.

A medical device manufacturer which knows or believes that its devices cannot be safely used in any segment of its patient population must make reasonable efforts to warn and instruct

its consumers regarding a restriction for those patients. According to the TVT-S IFU, the only restricted patient populations for the TVT-S were patients on anti-coagulation therapy and patients with urinary tract infections. This implied to physicians that the use of the TVT-S device in all other patients was acceptable. If Ethicon knew or believed that there may be risks specifically associated with the use of its TVT-S product in any given category of patients, it was obligated to so advise the physician users of the products.

#### **General causation opinions**

I am familiar with the published literature and the internal Ethicon documents describing complications associated with the TVT-Secur device, as discussed above. I have also personally observed, treated and explanted mesh from patients implanted with TVT-Secur.

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, as well as my review of internal Ethicon documents describing complications, it is my professional opinion to a reasonable degree of medical certainty that the injuries and complications that patients experience with the TVT-Secur and that I have personally observed, diagnosed and treated involving the TVT-Secur products are directly attributable to the defective design of these products as described previously. These complications include, but are not limited to, the following:

- 1. Chronic pelvic pain;
- 2. Chronic inflammation of tissue surrounding mesh;
- 3. Excessive scar plate formation and contracture of mesh, causing pain;
- 4. Erosion of mesh into the bladder and urethra and exposure of mesh in the vagina;
- 5. Pelvic floor muscle spasm;

- Direct trauma to organs and tissues and nerve injury and damage caused by the
   TVT-Secur insertion device;
- 7. Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging;
- 8. Dyspareunia;
- 9. Recurrence of stress urinary incontinence and urge incontinence;
- 10. Urinary retention;
- 11. Encapsulation of mesh (mesh covered in thick scar);
- 12. Vaginal deformation;
- 13. Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses; and
- 14. Fistulae.

#### III. DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the footnotes of this report, as well as those listed in Exhibit B attached hereto.

### IV. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of the TVT-Secur, and summaries of literature that I may prepare.

#### V. COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge \$1,000 per hour for review and study of records. I charge a 50% premium on records that must be reviewed within 30 days. Deposition fees are \$4,000 per half day and \$8,000 per full day. Court appearances are \$12,000 per day.

# VI. OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

P. Ashurst, Plaintiff Deposition, AZ; Attorneys: Rowley Chapman Barney & Buntrock

Bonnie Clarida, Plaintiff Deposition, GA; Attorneys: Ellerin & Associates

Donna Cisson v. C.R. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

DiLeonardo v. Boston Scientific, Plaintiff Deposition, GA; Attorneys: Shook, Hardy & Bacon, LLP

Crogan v Weinreb, Plaintiff Deposition, GA; Attorneys: Baxter, Baker, Sidle, Conn & Jones

Holizna v. Boston Scientific, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Russell v. Miklos, et al, Defendant Deposition and trial testimony, GA; Attorneys: Carlock, Copeland & Stair, LLP

Tonya Graves v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Rule 26 C.R.Bard MDL, Plaintiff Deposition, GA: Attorney: Blassingame, Burch, Garrard & Ashley

Atwell-Jackson v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Kathy Trammel v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Sandra Garcia v. Ethicon, GA; Attorneys: Clark, Love & Hutson

Hazel Lewis v. Bard, FL; Attorneys: Potts Law firm

Pamela Drebronkart v. Bard, GA; Attorneys: Levin Law firm

Beryl Cole v. Mentor Corp, GA; Attorneys: Potts Law firm

Elizabeth Way v. Bard, GA; Attorneys: Alystock, Witkin, Kreis & Overholtz

Melissa Watson v. Mentor, GA; Attorneys: Alystock, Witkin, Kreis & Overholtz

OHN MIKLOS, M.D.

<sup>&</sup>lt;sup>1</sup> ETH.MESH.00642330.

 $<sup>^2</sup>$  Cornu JN, et al. (2010) "Midterm prospective evaluation of TVT-Secur reveals high failure rate." Eur Urol. 2010 Jul; 58(1): 157-61.

<sup>&</sup>lt;sup>3</sup> ETH.MESH.0324086.

<sup>&</sup>lt;sup>4</sup> ETH.MESH.03922228 (10/25/07 internal e-mail).

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> ETH.MESH.00642330.

<sup>&</sup>lt;sup>8</sup> ETH.MESH.00312179.

<sup>&</sup>lt;sup>9</sup> A. Maree 7/22/13 depo., 189:14-190:22.

<sup>&</sup>lt;sup>10</sup> ETH.MESH.00823421.

 $<sup>^{1\</sup>mathrm{i}}$  Id.; See also, ETH.MESH.00874445; ETH.MESH.04126728.

<sup>&</sup>lt;sup>12</sup> ETH.MESH.04126728.

<sup>&</sup>lt;sup>13</sup> ETH.MESH.04127331.

<sup>&</sup>lt;sup>14</sup> ETH.MESH.04127062.

<sup>&</sup>lt;sup>15</sup> ETH.MESH.05009194.

<sup>&</sup>lt;sup>16</sup> ETH.MESH.04048515.

<sup>&</sup>lt;sup>17</sup> Hinoul P., et al., A randomized controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence. J Urol, 2011. 185(4): p. 1356-1362.

<sup>&</sup>lt;sup>18</sup> Nambiar A, et al., Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008709.

<sup>&</sup>lt;sup>19</sup> Hota, Lekha S., MD, et al., TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. Female Pelvic Med Reconstr Surg. 2012, Jan-Feb; 18(1): 41-45 (47% cure rate for the TVT-Secur versus 91% cure rate for the TVT-O); Maslow K, et al. Randomized clinical trial comparing TVT Secur system and trans vaginal obturator tape for the surgical management of stress urinary incontinence. Int Urogynecol J (2014) 25:909-914 (63% cure rate for the TVT-Secur versus 86% cure rate for TVT-O). Hamer MA, Larsson PG, Teleman P, Bergquist CE, Persson J. One year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogyn J (2013) 24:223-9. Wang Y, Li F, Wang Q, Yang S, Cai X, Chen Y (2011) Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 22:1369–1374

<sup>&</sup>lt;sup>20</sup> ETH.MESH.00327062

<sup>&</sup>lt;sup>21</sup> Deposition of Dr. David Robinson, 7/24/13, page 116, lines 5-22.

<sup>&</sup>lt;sup>22</sup> ETH.MESH.04474756 (In a study conducted by Ethicon-consulting Key Opinion Leader physicians, the authors concluded that "there was also an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is unclear, we theorize that the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in higher erosion rates.").

<sup>&</sup>lt;sup>23</sup> ETH.MESH.0329316 (11/6/06 internal e-mail to Ethicon Medical Director revealing issue regarding removal of TVT-S device upon removal of insertion device, and concerns of high rates of injuries when the mesh does not separate from insertion device during removal, causing the mesh to be moved or pulled out with the inserter); ETH.MESH.00572598 (5/17/07 presentation by Ethicon European Medical Director) ("Key Issues in Europe" include "[s]ome key experts and non-experts are disappointed [in TVT-S]," and "[k]ey experts are abandoning the procedure.").

<sup>&</sup>lt;sup>24</sup> ETH.MESH.06051286.

<sup>&</sup>lt;sup>25</sup> ETH.MESH.02105223.

<sup>&</sup>lt;sup>26</sup> Rahmy Mahmoud, M.D. 7/16/13 depo., 380:5-10.

<sup>&</sup>lt;sup>27</sup> ETH.MESH.03922618 (3/14/07 internal e-mail from Ethicon Medical Director to Ethicon European Medical Director stating that first human study revealed "that the learning curve is longer than we thought, mesh tensioning is different than kits with sheaths and that following the IFU is important."); ETH.MESH.02105223 (8/19/07 Worldwide Marketing Team Update PowerPoint on TVT-S) (noting TVT-S learning curve was longer than anticipated, that there was a "lack of right training," and a "lack of clinical data.").

<sup>&</sup>lt;sup>28</sup> ETH.MESH.00858636.

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> ETH.MESH.02105223.

<sup>&</sup>lt;sup>31</sup> ETH.MESH.03845446, p. 1.

<sup>&</sup>lt;sup>32</sup> ETH.MESH.04048515 (6/18/08 internal report), p. 3.

<sup>&</sup>lt;sup>33</sup> ETH.MESH.00642325, p. 3.

<sup>&</sup>lt;sup>34</sup> Id.

<sup>&</sup>lt;sup>35</sup> ETH.MESH.01784428, pp. 2-3.

<sup>&</sup>lt;sup>36</sup> Id., p. 1.

<sup>&</sup>lt;sup>37</sup> ETH.MESH.00642330.

<sup>&</sup>lt;sup>38</sup> ETH.MESH.00642327.

<sup>&</sup>lt;sup>39</sup> ETH.MESH.0329557 (3/1/07 internal e-mail indicating more than 50 reports of TVT-S failures with some requiring intervention, to which Ethicon responded by sending engineer Dan Smith to "retrain preceptors and others."); ETH.MESH.02105223 (8/19/07 internal PowerPoint) (noting "lack of local budgets [for TVT-S training] leading to local decision for self trained surgeons (CD, sales force)"). See also, ETH.MESH.00330141.

<sup>&</sup>lt;sup>40</sup> ETH.MESH.00874445, p. 17.

<sup>&</sup>lt;sup>41</sup> ETH.MESH.04092868 (12/19/08 internal e-mail).

<sup>&</sup>lt;sup>42</sup> ETH.MESH.04094863 (1/29/09 internal e-mail).

<sup>43</sup> ETH.MESH.04092868.

<sup>&</sup>lt;sup>44</sup> ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) - "Polypropylene - initial acute inflammation then chronic foreign body reaction."); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material...."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.00680021 (11/12/08 internal e-mail) – "Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh."); ETH.MESH.03722384 (9/17/09 internal e-mail) – "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction...Might be better off working with something that is less reactive, like PVDF."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.""); ETH.MESH.05237872 (Nov. 3-4, 2010 "Mesh and Textile Summit") – PowerPoint addressing downsides of "old fashioned" (i.e., polypropylene mesh): "Excessive foreign body reaction; Chronic inflammation; Decreased fibro collagenous ingrowth; Scar plate formation; Shrinkage from bridging fibrosis.").

<sup>&</sup>lt;sup>45</sup> ETH.MESH.01037447, p. 6 (TVT-S Clinical Expert Report prepared by Ethicon Medical Director indicating abnormal bleeding, hematuria, leg pain, hematoma, venous thrombosis, abscess formation, and death as potential TVT-S complications).

<sup>&</sup>lt;sup>46</sup> ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon"s European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."). ETH.MESH.01752532 (9/18/06 internal e-mail) - "As soon as meshes are considered as a prosthesis in the pelvic floor region, the biomechanical consequences of implantable meshes are not without concern. The body generates an inflammatory response to the prosthetic that results in more ore less sever scar plate formation, increased tissue stiffness and possible shrinkage of the mesh."); ETH.MESH.02247342 (1/21/09 internal PowerPoint) "Importance of Pore Size. Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction to heavyweight Polypropylene tends to form a scar plate around the prosthetic that results in a firm and contracted mesh...Bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half to the pore size of the mesh. Desirable pore size >1mm. [citing literature from 2005 and 2006].").

<sup>47</sup> ETH.MESH.03910418 (11/25/02 internal e-mail regarding, inter alia, mesh shrinkage in TVT) - "As we discussed the shrinkage rate is influenced by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that Axel [Arnaud, Ethicon's European Medical Director was using 30% shrinkage as a rule of thumb...."); (ETH.MESH.00584846 (5/10/04 internal e-mail) – "Their [consulting physicians"] main concern is now the shrinkage of the mesh which may lead to pain, dyspareunia... Indeed now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh (in this case Gynemesh soft)."); ETH.MESH.00681364 (9/07/04 internal report) – "GYNEMESH PS today has a 'swirling effect' causing what doctors have expressed as 'shrinkage or contraction of the mesh'. It isn't the mesh that's contracting, it's the tissue that seems to be 'bunching' up resulting in the desire to have a more 'tension-free' fixation."); ETH.MESH.05574759 (1/18/05 internal e-mail reporting surgeon"s experience with use of Gynemesh in pelvic floor repair) – "a. contraction pulls against the side wall and causes pain b. it causes a hard tissue which can be felt by patient and sexual partner c. it can lead to a balling up of the mesh which is very uncomfortable d. it can lead to suture line dehiscence e. it can lead to prolapse recurrence.... 5) he confirmed our thoughts regarding the correlation between inflammation, foreign body response and scar formation."); ETH.MESH.05246528 (3/10/05 report discussing areas impacting clinical outcomes with mesh) – "Tissue contraction (20-40%), Scar formation = recurrence or dyspareunia... Erosions - potentially address through technique."); ETH.MESH.04020138 (4/13/05 e-mail from Ethicon engineer) – "In pelvic floor repair even with the PSM, we have seen some scar contracture which translates into procedural complications... [S]urgeons who are our consultants on the Prolift product are asking for a mesh which is better than PSM in this area." (Id.). "The surgeons attribute these conditions [recurrence of prolapse, pain, stiffness, erosion and discomfort during sex] to scar contracture."); ETH.MESH.03906579 (6/09/05 interview with Ethicon European Medical Director, Axel Arnaud) – "Shrinkage is due to an excessive scarring process...in a few cases it led to vaginal distortion impacting the sexual life. Thus, the procedure must be used cautiously in sexually active women."); ETH.MESH.05243265 (1/24/06 e-mail discussing meeting with consulting physicians in Europe) – "Their [physicians"] main concern is the believe that the Prolene Soft material over time contracts. Thus creating the potential for failures and/our erosions."); ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon"s European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."); ETH.MESH.00870466 (6/2/06 Expert Meeting Memo) ("Shrinkage of 20% means reduction of mesh area to 64%."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – ""Shrinking meshes" are a topic of discussion and concern among hernia surgeons. It is believed that mesh shrinkage may lead to patients' discomfort, chronic pain or hernia recurrence.... Mesh shrinkage was evaluated at different time points and the reduction of the calculated area was 12% at one month, 24% at 3 months, 29% at 6 months and 34% at 12 month. [citing 2006 literature]"); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material... Unmet clinical needs: No shrinkage/no long term contraction... Severe contraction →

Dyspareunia  $\rightarrow$  sexual function  $\downarrow$ ."); ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift), Slide 23 – ("Functional results: painful mesh shrinkage. Painful mesh shrinkage (at vaginal examination) – 21 patients (19.6%).... Correlation between painful mesh shrinkage and dyspareunia but not systematic."); ETH.MESH.01818382 (12/20/07 Ethicon Mesh Contraction preclinical study) (27% shrinkage (measured radiographically) and 23% (measured by image analysis), as well as fibrotic bridging, folding, rippling and distortion, for Prolene Soft in the subcutaneous model after 13 weeks implantation); ETH.MESH.00836975 (3/28/08 internal e-mail from Ethicon Worldwide Medical Director responding to question about how to identify and complications associated with mesh shrinkage) - "First, the mesh doesn't shrink. As collagen grows into the mesh, the entire mass contracts.... In the patient, it can be noted with stiffening of the vaginal wall (causing dyspareunia) or bunching of the Prolift straps (which can cause pain). All patients getting mesh get contraction."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.02227282 (11/14/09 PowerPoint), p. 7 – "Folding of mesh is one cause for erosion and pain."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) - "There is no place for a "Heavyweight Mesh" in modern pelvic floor repair... Polypropylene Mesh – Small pore size (<1 mm)... Issues with small pore meshes –...Increased inflammatory response results in rigid scar plate formation – Scar plate responsible for shrinkage of mesh up to 40% [citing published literature from 2002 and 2004].").

<sup>48</sup> ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve) ..... Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH\_ETH\_01800994 (10/11/06 internal e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device.... [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the "foreign body reaction" is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.").

<sup>&</sup>lt;sup>49</sup> ETH.MESH.08167452 (10/3/00 internal e-mail in response to e-mail from physician consultant regarding instructions for TVT removal procedure) – "Theoretically, I can envisage no need for TVT explant. And I agree…that if we, in any way, publish such an information, we start giving the reason to believe that explant of the TVT may be needed in some circumstances. Frankly, I do not want to dig my own grave…!"…"In my opinion, we must be very careful in avoiding 'overinformation'").

<sup>&</sup>lt;sup>50</sup> ETH.MESH.00519479.

<sup>&</sup>lt;sup>51</sup> ETH.MESH.02105223.

<sup>&</sup>lt;sup>52</sup> ETH.MESH.06051155.

<sup>&</sup>lt;sup>53</sup> ETH.MESH.00312180.

#### **CERTIFICATE OF SERVICE**

I hereby certify that on February 1, 2016, I served the **PLAINTIFFS' RULE 26(a)(2)(B) EXPERT REPORT OF JOHN MIKLOS, M.D.** on the following counsel of record by electronic mail:

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### **EXHIBIT "B"**

DR. JOHN MIKLOS	
Bates Number	Description
ETH.MESH.11336216- ETH.MESH.11336225	Ten Year In Vivo Study: Scanning Electron and Light Microscopy Interim Report on Dog #1995 After 6 Years, 10.5 Month, SR#33788, dated May 29, 1992
	Klinge, Otto, Muhl. "High Structural Stability of Textile Implants Prevents Port Collapse and Preserves Effective Porosity at Strain," BioMed Research International, Vol. 2015, 7 pp.
	Gigliobianco, Regueros, Osman, et al. "Biomaterials for Pelvic Floor Reconstructive Surgery: How Can We Do Better?" BioMed Research International, Vol. 2015, 20 pp.
	Williams, David. "There is no Such Thing as a Biocompatible Material," Biomaterials 35 (2014) 10009-10014.
	Williams, David. "On the Mechanisms of Biocompatibility," Biomaterials 29 (2008) 2941-2953.
	Mazza, Ehret. "Mechanical Biocompatibility of Highly Deformable Biomedical Materials," Institute of Mechanical Systems, pp. 1-47.
	Procedural Videos Prolift - Lucente Anterior and Posterior movie clips Prolift - Sepulveda - Case 1 and 2 movie clips TVT - complete, device, intro and prep movie clips
	IFU Notebook
ETH.MESH.02342194- ETH.MESH.02342196	<b>Gynemesh Prolene Soft Instructions for Use</b> - Instructions in use from 3/20/2003 to 3/30/2006.
ETH.MESH.02342278- ETH.MESH.02342279	<b>Gynemesh Prolene Soft Instructions for Use -</b> Instructions in use from 3/31/2006 to 12/11/2008.
ETH.MESH.02342250- ETH.MESH.02342252	<b>Gynemesh Prolene Soft Instructions for Use -</b> Instructions in use from 12/12/2008 to the Present
ETH.MESH.02342218- ETH.MESH.02342220	<b>Gynemesh Prolene Soft Instructions for Use -</b> Instructions in use from 3/10/2009 to Present Day.
ETH.MESH.02341522- ETH.MESH.02341527	<b>Prolift Instructions for Use -</b> Instructions in use from 1/11/2005 to 12/13/2007
ETH.MESH.02341454- ETH.MESH.02341459	<b>Prolift Instructions for Use -</b> Instructions in use from 12/17/2007 to 9/24/2009
ETH.MESH.02001398- ETH.MESH.02001404	<b>Prolift Instructions for Use -</b> Instructions in use from 10/1/2009 to 5/7/2010

ETH.MESH.02341658-	Prolift Instructions for Use - Instructions in use from
ETH.MESH.02341664	5/11/2010 to Discontinuance
ETH.MESH.01595614-	Prolift+M Instructions for Use - Instructions in use from
ETH.MESH.01595619	12/12/2008 to 1/13/2011.
ETH.MESH.02615519-	Prolift+M Instructions for Use: Instructions in use from
ETH.MESH.02615524	2/4/2011 to discontinuance.
	2/4/2011 to discontinuance.
ETH.MESH.05225354; ETH.MESH.05225380-	TVT Instructions for User Instructions in use from 0/0/2000 to
	TVT Instructions for Use: Instructions in use from 9/8/2000 to
ETH.MESH.05225384	11/26/2003
ETH.MESH.02340306;	TVT land modified a few Head land modified a few as force 40/00/0000
ETH.MESH02340331-	TVT Instructions for Use: Instructions in use from 12/22/2003
ETH.MESH.02340335	to 2/11/2005
ETH.MESH.02340471;	
ETH.MESH.02340484-	TVT 1 ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (
ETH.MESH.02340486;	TVT Instructions for Use: Instructions in use from 2/11/2005
ETH.MESH.02340499	to 4/7/2006
ETH.MESH.05222673;	
ETH.MESH.05222686-	
ETH.MESH.05222688;	TVT Instructions for Use: Instructions in use from 4/7/2006 to
ETH.MESH.05222701	10/7/2008
ETH.MESH.02340504;	
ETH.MESH.02340529-	
ETH.MESH.02340533;	TVT Instructions for Use: Instructions in use from 10/13/2008
ETH.MESH.02340560	to 11/22/2010
ETH.MESH.03427878-	TVT Instructions for Use: Instructions in use from 11/29/2010
ETH.MESH.03427883	to Present Day
ETH.MESH.02340829-	TVT-O Instructions for Use: Instructions in use from 1/7/2004
ETH.MESH.02340835	to 3/4/2005
ETH.MESH.02340756-	TVT-O Instructions for Use: Instructions in use from 3/7/2005
ETH.MESH.02340762	to 5/19/2005.
ETH.MESH.02340974-	TVT-O Instructions for Use: Instructions in use from
ETH.MESH.02340980	5/25/2005 to 4/29/2008.
ETH.MESH.00860239-	TVT-O Instructions for Use: Instructions in use from
ETH.MESH.00860245	4/23/2008 to 5/7/2010
ETH.MESH.02340902-	TVT-O Instructions for Use: Instructions in use from
ETH.MESH.02340908	5/12/2010 to present day.
ETH.MESH.02340568-	TVT-Secur Instructions for Use: Instructions in use from
ETH.MESH.02340590	12/16/2005 to discontinuance.
L 11 1.WE OI 1.02040330	12/10/2000 to discontinuance.
	ALL ETHICON MESH PRODUCTS NOTEBOOK
	Crack Depth in Explanted PROLENE Polypropylene
	Sutures: Memo on a study which found Prolene sutures
ETH.MESH.12831405 -	showed surface cracks after implantation and table of crack
ETH.MESH.12831406	depth
L 11 1.1VILOI 1. 1200 1700	dopul

	IR MICROSCOPY OF EXPLANTED PROLENE - Memo about
ETH.MESH.12831391 -	samples that were pulled from a human graft and examined for
ETH.MESH.12831404	cracking
	PROLENE EXPLANTS STUDY MEETING MINUTES 10/8/87 -
	A meeting was held to discuss the status of the study on
ETH.MESH.12831407 -	PROLENE*
ETH.MESH.12831408	explants
	SEVEN YEAR DATA FOR TEN YEAR PROLENE STUDY -
ETH.MESH.09888187 -	This report contains a summary of IR, IV, GPC, OM and SEM
ETH.MESH.09888223	data.
	INTEGRATED PROJECT UPDATE: MARCH - An update that
ETH.MESH.03544317 -	includes the assessment, concept, feasibility, development and
ETH.MESH.03544328	implantation of the products
	Characteristics of NGP Polymer Material and Its Sutures -
ETH.MESH.05521275 -	A memo that discusses in depth about the NGP Polymer
ETH.MESH.05521278	material and its properties
	PRONOVA lpoly(hexafluoropropylene-vinylidene fluoride)]
	Non-Absorbable Suture USP -
	Position Statement to Support Clinical Safety and Efficacy -
	A letter supporting the clinical safety of Pronova which
ETH.MESH.08505072 -	includes biostability assessment, biocompatibility
ETH.MESH.08505076	assessment, preclinical efficacy, and clinical experience
	Meshes in Pelvic Floor Repair - Findings from literature
ETH.MESH.03904451 -	review and
ETH.MESH.03904480	conversations/interviews with surgeons
	DDONOVA O 4 m. A New Down on Business and Blist I.
	PRONOVA Suture: A New Damage Resistance and Pliable
LIMEOU ETU 00740045	Non-absorbable Monofilament Suture - A memo discussing
	lithe a shows a management and file are not a management in a construction of the standard of
HMESH_ETH_06743815 -	the polymer preparation, filament preparation, and materials
HMESH_ETH_06743815 - HMESH_ETH_06743819	the polymer preparation, filament preparation, and materials and methods of the Pronova suture
	and methods of the Pronova suture
	and methods of the Pronova suture  Pelvic Floor Repair Email - An email that discusses a report
	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss
HMESH_ETH_06743819	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of
HMESH_ETH_06743819  ETH.MESH.08167462 -	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of the stats in the report are just rumors (in reference to TVT
HMESH_ETH_06743819	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of
HMESH_ETH_06743819  ETH.MESH.08167462 -	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of the stats in the report are just rumors (in reference to TVT erosion)
HMESH_ETH_06743819  ETH.MESH.08167462 -	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of the stats in the report are just rumors (in reference to TVT erosion)  Pelvic Floor Repair Email - This is an email responding to the
HMESH_ETH_06743819  ETH.MESH.08167462 -	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of the stats in the report are just rumors (in reference to TVT erosion)  Pelvic Floor Repair Email - This is an email responding to the email referenced above. The response discussed the minimum
HMESH_ETH_06743819  ETH.MESH.08167462 - ETH.MESH.08167465	Pelvic Floor Repair Email - An email that discusses a report on meshes used for pelvic floor repair. The recipients discuss the pros and cons of each and how they believe that some of the stats in the report are just rumors (in reference to TVT erosion)  Pelvic Floor Repair Email - This is an email responding to the

	Project Edelweiss PD 01 /03: Notes from Meeting of
	2.8.2001 - A memo that discusses the project goal of
ETH.MESH.05644808 -	accelerating the transformation to large pore size meshes and
ETH.MESH.05644810	what may go into doing so
ETH.MESH.05495497 -	Notes from European Mesh Meeting Sept. 5, 2001 - Notes
ETH.MESH.05495502	from a meeting that discussed Project Edelweiss PD 01/03.
	,
ETH.MESH.05644320 -	Project Edelweiss PowerPoint - A powerpoint that compares
ETH.MESH.05644322	the possible material choices, Pronova or Prolene
	Invention Disclosure Form - A invention disclosure form for
	Polyoxyester as a tissue engineering material for replacement
ETH.MESH.06000873 -	of muscle,
ETH.MESH.06000875	ligament, fascia and other tissue types
E111.WESI1.00000073	ligament, rascia and other tissue types
	Ethican Surgeon Banal Mosting: Mash - A mosting where
ETH.MESH.05455878 -	<b>Ethicon Surgeon Panel Meeting: Mesh -</b> A meeting where the focus was the future of abdominal wall repair. It has notes
	·
ETH.MESH.05455898	from the numerous presentations which support the focus.
	Powerpoint Presentation : Graft or No Graft - This
ET.   1450    0555 4050	presentation explores the various ways of going about repairing
ETH.MESH.05574856 -	the pelvic floor, the pros and cons of each, and risks
ETH.MESH.05574856	associated
	Titanium Mesh Email - An email that discusses the advanced
ETH.MESH.03928132 -	mesh materials in order to try reducing erosions and shrinkage;
ETH.MESH.03928133	in addition to potential pros and cons
	Proposal for Work with CBAT - An email that discusses the
	approval for project approval. It also discusses important points
ETH.MESH.05574759 -	a professor made in regards to problems he is having with
ETH.MESH.05574761	mesh
	Minutes Hamburg Meeting June 2nd: Email - An email that
ETH.MESH.00870465 -	contains the minutes from the New Mesh for Pelvic Floor
ETH.MESH.00870476	meeting.
	Mesh design argumentation issues - A report that looks at
ETH.MESH.01752532 -	the biomechanical
ETH.MESH.01752536	consequences of implantable meshes and their concerns
2111.W2611.017 02000	consequences of implantable meetics and their concerns
	State of the knowledge in mesh shrinkage - This report
	discusses the product requirements of a next generation mesh
	in terms of less shrinkage. The goal of this research was to find
	out what is currently known about mesh shrinkage
ETU MESU 10511700	·
ETH.MESH.10511708 -	and which factors (on the patients' side as well as on the mesh
ETH.MESH.10511712	side) influence mesh shrinkage.

ETH.MESH.02017152 - ETH.MESH.02017158	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair - This memo lists the notes from the various presentations presented at the meeting (Lighting project, experiences with UltraPro, factors related to shrinkage, ideal pelvic floor repair)
HMESH_ETH_02860031 - HMESH_ETH_02860032	How inert is polypropylene Email - This email discussed the results of the dog study in regards to Prolene and Pronova sutures. In addition, it discusses the challenges from other professionals that they are facing
ETH.MESH.05588123 - ETH.MESH.05588126 and KE-001773913 - KE-001773913	How inert is polypropylene Email Response - This is a response to the above email. This email contains information about various test results and how those will effect the future
ETH.MESH.00869907 - ETH.MESH.00869909	Minutes Call Email - An email with the minutes from the Thunder Team call. The covered the following: project overview, marketing, medical/clinical, upstream, R&D, and miscellaneous
ETH.MESH.05878696 - ETH.MESH.05878699	Implantation Study Pronova vs Prolene Email - An email that includes a statement by Dr. Bernd Klosterhalfen on the implantation and evaluation of Pronova mesh compared to Prolene mesh of the same textile structure. In short the study ran for a year and showed an improved biocompatibility of the Pronova Meshes over the Prolene Meshes.
HMESH_ETH_00128788 - HMESH_ETH_00128789  HMESH_ETH_03293608 - HMESH_ETH_03293611	Implantation Study Pronova vs Prolene Email Response - A response to the email above. There is discussion about a study already being successfully completed and how they plan to present this information.  Prolene Hernia System Email - An email discussing the updates needed, the characteristics of mesh and how all mesh shrinks.
ETH.MESH.02588170 -	Powerpoint Presentation - A powerpoint presentation that discusses mesh characteristics and states how no mesh is the best mesh.

	Matrix Material Powerpoint Presentation - a powerpoint that
	states that matrix material is a powerful new tool in Advanced
	Tissue Reconstruction. The powerpoint covers unmet needs,
ETH.MESH.02247337 -	goals, visions, existing technology, concerns, studies and
ETH.MESH.02247337	potential ideas
	Thunder MGPP Decision Meeting Powerpoint - A
	powerpoint that displays the topics covered during the Thunder
	Meeting which include customer feedback on PFR devices,
ETH.MESH.02141727 -	potential roles, value propositions, various options, next steps
ETH.MESH.02141727	and study comparisons
	T-Pro (Thunder) Pipeline Leadership Team Powerpoint - A
	powerpoint that gives the background and overview of T-Pro.
	In addition, it covers the marketing opportunity model, design
ETH.MESH.02142351 -	considerations, techniques, published data, target product
ETH.MESH.02142351	profile, product vision, needs, and future plans
	Pre-Reading for PROLIFT+M Email - An email that discusses
	that reps need to be conversant with is: Phases of wound
	healing, Comparative properties of various grafts, Mechanical
	of mesh integration including the important of port size, the
ETH.MESH.00271215 -	phenomenon of scar bridging as it pertains to various grafts, the concept of hyperelasticity, and the use of animal models in
ETH.MESH.00271216	the histological studies of wound healing (+ grafts)
ETH:MESH.00271210	the histological studies of wound healing (+ grants)
	PROLIFT+M Pre-reading #1 Email - An email that
	communicates to the reps of the required reading they will
ETH.MESH.00680021 -	need to do. It also summarizes the highlighted/important
ETH.MESH.00680022	concepts out of the nine articles
	The Future of Surgical Machaer The Industry's Baranastive
	The Future of Surgical Meshes: The Industry's Perspective
ETH.MESH.01203957 -	<b>Powerpoint -</b> A powerpoint that covers all the characteristics and concepts of mesh and the results of various studies and
ETH.MESH.01203957	how these things will effect future mesh.
L 11 1.WL 31 1.0 1203931	now these things will effect luture mesh.
	Matrix Thunder Avatar Plus Add to Meeting List Email - An
	email that discusses the overview of lightweight implants,
ETH.MESH.02310496 -	compare the strengths/features/goals, reviews the different
ETH.MESH.02310502	types of studies and lists the possible projects.

ETH.MESH.09650757 - ETH.MESH.09650767	Invention Disclosure Form - An invention disclosure form for
ETH.IMESH.09030707	Areal implant with body embedded properties.
ETH.MESH.09650853 - ETH.MESH.09650863	Invention Disclosure Form - An invention disclosure form for Areal implant with body embedded properties.
	r a car arripram a construction properties.
	Development of a Novel Preclinical Model to Evaluate
	Advanced Tissue Constructs for Pelvic Floor Repairs - A
HMESH_ETH_02034931 -	slide that includes the abstract, introduction, Methods and
HMESH_ETH_02034931	Conclusion of developing a novel preclinical model
	When the implant worries the body Powerpoint - A
ETIL MEQUA 04707070	powerpoint that goes over stiff implants, different testing
ETH.MESH.01787870 -	methods and how they give different results, varying mesh
ETH.MESH.01787870	sizes and physiological demands
	Medical devices created from PVDF Blend polymers - his
	memo is in response to the communication dated April 21,
	2009 between James Williams (Ethicon) and Rossella Ingoglia
	(Sovay Solexis SpA). In that communication, follow-up
ETH.MESH.15377373 -	questions were asked to better understand application areas
ETH.MESH.15377374	and expected duration of the medical device in-vivo.
	Mesh + Anti-proliferative agent Email - An email discussing
ETI I MEQLI 0070004	seeing a lot of work published that indicates that polypropylene
ETH.MESH.03722384 -	produces an ongoing, chronic inflammatory reaction and other
ETH.MESH.03722386	side effects.
	Discovery Project T-Pro (NG PROLIFT):1st Material
	designed for Female Pelvic Floor Powerpoint - A
	powerpoint used during EWH&U Engineering Review 10/22/09.
ETH.MESH.00751733 -	It includes competitive markets, different projects and their
ETH.MESH.00751733	goals and the history of innovative mesh solutions
	Updated T-PRO Deck Email - An email sharing the updated T-
	Pro Powerpoint with all of the reps. The update included
	switching slides around and including some further pictures
ETH.MESH.02227282 -	and studies. This presentation also goes more in depth in
ETH.MESH.02227283	regards to surgical needs and procedures.

HMESH_ETH_00228961 - HMESH_ETH_00228973	PRONOVA properties Email - An email with discussions about the attached powerpoint. The powerpoint is about WHU Thunder Pronova Characteristics and Prototype Screening in vivo (Histology, Biomechanics and stability)
HMESH_ETH_00240446 - HMESH_ETH_00240446	<b>EWHU R&amp;D Projects Powerpoint -</b> A powerpoint that discusses the prevalence of pelvic organ prolapse, different concept overviews, and different projects
	Need your help Email - An email discussing the first post-
ETH.MESH.04101843 -	operative patient death associated with intra-operative use of
ETH.MESH.04101847	Pronova Suture
ETH.MESH.10578304 - ETH.MESH.10578306	PA Consulting Group Meeting: Mesh Erosion Interview: Pathology - A memo containing the minutes to the Consulting Group meeting. They discussed the many variables that effect the erosion of mesh.
ETH.MESH.05916450 - ETH.MESH.05916450	Chronic Pain: Prevention/Future: Bioengineer's point of view Powerpoint Presentation - A powerpoint that covers the influencing factors, what causes the pain, how mesh is related, validation of results and recommendations
ETH.MESH.05237872 - ETH.MESH.05237872	Mesh Properties: How Important are they Powerpoint Presentation - A powerpoint that discusses polypropylene mesh, old fashioned mesh, issues faced, pain, construction, shrinkage, comparing different types of mesh and recommendations
ETH.MESH.05479695 - ETH.MESH.05479695	Mesh Innovation for Pelvic Floor Repair Powerpoint Presentation - A powerpoint that discusses what the ideal mesh is for pelvic floor repair, various requirements, and various options
ETH.MESH.07192929 - ETH.MESH.07192929	Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint Presentation - A powerpoint that discusses the rate of complications, how to investigate, the family of meshes, important factors, influences of erosion, product comparisons and suggestions

ETH.MESH.14445346 - ETH.MESH.14445347	Pronova presentation for international call Email - An email that describes the attachment and what will be discussed during the call. It includes introducing the project FREELIFT, background on the requirements for a potential FREELIFT mesh, and literature talking about PRONOVA and PVDF results (mesh and suture).
HMESH_ETH_06944572 - HMESH_ETH_06944575	PRONOVA as mesh raw material for project FREELIFT Email - An email discussing the possibility of experts to use PRONOVA as raw material for the future mesh component of the FREELIFT implant (will be used for prolapse surgery). In addition, it included a development report
ETH.MESH.15223385 - ETH.MESH.15223386	Minutes for the PRONOVA discussion Jan-18 2012 Email - an email that included the highlights from the minutes of the Pronova discussion meeting
HMESH_ETH_03549498 - HMESH_ETH_03549501	Leftovers from SECURSTRAP Email - An email that discusses working on project FREELIFT (EWHU) and thinking about PALG20-85 as possible polymer for the new product. The email discusses about possible options and if there were any spare parts left over from previous projects
HMESH_ETH_06865166 - HMESH_ETH_06865168	Pronova Email - This email discusses the different projects and what is going on with each other them. In addition, it talks about what can effect drape.
ETH.MESH.07726991 - ETH.MESH.07726994	CLAVE Publication: Ethicon Response Appointment - This appointment reminder is for a meeting to discuss the latest responses on the CLAVE paper and talks about what the attendees need to do prior to the meeting
HMESH_ETH_00120151 - HMESH_ETH_00120152	Mesh questions Again Email - This email discusses various questions about pore size for different products
ETH.MESH.05644163 - ETH.MESH.05644171	Pelvic Floor Repair : Surgeon' s Feed-back on Mesh Concept - A memo that discusses a surgeon's feeling on pelvic floor repair, the reason's behind it and the products used

	Value Propositions: Edelweiss - A situation analysis of
	various situations a repair surgeon can face. In addition, it
ETH.MESH.05644700 -	covers features and benefits, product description and value
ETH.MESH.05644704	proposition
ETT.:WESI 1:030447 04	proposition
	Implant Comparison A comparison between Brolens and
ETILMECILOSCA4040	Implant Comparison - A comparison between Prolene and
ETH.MESH.05644940 -	Pronova that includes biocompatibility, general properties, and
ETH.MESH.05644942	bacterial adhesion
ETIL ME 011 000 4500 4	Agenda Email - An email that discusses the concern about
ETH.MESH.00845621-	lack of alignment of IFUs for a product as new iterations come
ETH.MESH.00845621	about.
	Review Email - An email with an attachment that is used for
ETH.MESH.02307214-	review. The email discusses that there is an upcoming NTM
ETH.MESH.02307242	and a minor exam the reps will be encountering.
	Procedural steps Email - An email with an attachment that
ETH.MESH.08174059-	lists all the procedural steps for the different pelvic repair
ETH.MESH.08174071	procedures
	Prolift Notebook
ETH.MESH.19874581-	Prolift plus M Email - An email that discusses what the status
ETH.MESH.19874582	of the Prolift plus M graft
	Mesh for TVM Email - An email that discusses some input
ETH.MESH.00584846 -	from the Gynecare European unit regarding mesh used for
ETH.MESH.00584847	pelvic floor repair.
ETH.MESH.03928881 -	IFU Prolift Email - An email about potential new additions to
ETH.MESH.03928882	the IFU's
ETH.MESH.02286052 -	<b>IFU Prolift Email</b> - An email discussing if items can be added
ETH.MESH.02286053	to the IFU without FDA approval
ETIL ME 011 050 40505	Next Generation Mesh Discussion - A memo/minutes from a
ETH.MESH.05246527 -	meeting that covers reviewing current priorities, future
ETH.MESH.05246528	direction, owners and timelines
	ICS submission Email - An email discussing
ETH.MESH.06828907 -	understanding/assumptions/requests regarding the
ETH.MESH.06828909	submissions.
	ULTRAPRO vs PROLENE Soft Mesh Email - An email that
ETH.MESH.04020138 -	discusses information that was presented to them and where
ETH.MESH.04020145	there are issues and/or questions
	·
	Press Interview - A memo discussing a demonstrative slide
ETH.MESH.03906576 -	showing what a prolapse really is and emphasize it is a very
ETH.MESH.03906579	common issue in women.
ETH.MESH.02923305 -	PROLIFT email - An email discussing safety information and
ETH.MESH.02923306	efficacy data
L 11 1.1VIL OI 1.02020000	Joineday data

	Prolift Mesh (Gynecare) for Pelvic Organ Prolapse Surgical Treatment Using Tension-free Vaginal Mesh: Presented at ICS - A memo discussing Pelvic Organ Prolapse and the
ETH.MESH.00877490 -	techniques used to treat. In addition, it refers to different
ETH.MESH.00877491	studies and data
E111.WESI1.00077491	Studies and data
	DDOLLET Insurance to Dr. Charley d. /Crossenfold
ETI I NEOLI 00044004	PROLIFT Improvements: Pr Eberhard (Frauenfeld,
ETH.MESH.03911684 -	Switzerland) Email - An email discussing needing to think
ETH.MESH.03911687	about how and what they will change in Prolift.
ETH.MESH.05243265 -	TVM discussions Email - An email discussing the concerns
ETH.MESH.05243265	that were brought up during a TVM meeting
	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair - A
ETH.MESH.00870466 -	memo of minutes from a meeting that discuss the highlights of
ETH.MESH.00870476	a presentation
	Clinical Study Report: Evaluation of the TVM technique for
	treatment of genital prolapse - This is the study of the
ETH.MESH.00012009 -	Evaluation of the TVM technique for treatment of genital
ETH.MESH.00012089	prolapse
ETH.MESH.03160750 -	Pelvic Floor/Mesh Strategy Email - An email that discusses
ETH.MESH.03160752	the Lighting project and Prosima
ETH.MESH.00267733 - ETH.MESH.00267872	Lighting Project Charter Powerpoint Presentation - A powerpoint that discusses the marketing plans, financial plans and visions for the project. In addition, it discusses the customer needs and project milestones
ETH.MESH.01774758 -	PROLIFT Mesh Design Email - An email discussing ideas for
ETH.MESH.01774760	the upcoming projects and products
ETH.MESH.03912616 -	PROLIFT Mesh Design Email - An email discussing ideas for
ETH.MESH.03912618	the upcoming projects and products
	Ethicon Expert Meeting : Meshes for Pelvic Floor Repair -
	This memo lists the notes from the various presentations
ETH.MESH.02017152 -	presented at the meeting (Lighting project, experiences with
ETH.MESH.02017158	UltraPro, factors related to shrinkage, ideal pelvic floor repair)
ETH.MESH.03536600 -	Pain after Prolift Email - An email discussing complaints
ETH.MESH.03536602	about Prolift
ETH.MESH.00067354 -	Q&A transcription Email - An email with an attachment that is
ETH.MESH.00067363	the transcript from the +M webinar.

	SLU Uro-GYN Follow-up Email - An email that discusses how
ETH.MESH.08367243 -	upset a doctor is about a patient who has permanent damage
ETH.MESH.08367244	from one of the products
	Brolift . M (Lightning) Bookground Information from BSD
	Prolift +M (Lightning) Background Information from R&D Powerpoint Presentation - This powerpoint discusses the
ETH.MESH.05237919 -	improvements customers expect, project candidates, and
ETH.MESH.05237919	product overview including characteristics
ETH.MESH.01238483 -	Prolift +M vs. Pinnacle - A memo that compares Prolift +M
ETH.MESH.01238484	and Pinnacle
ETH.MESH.04097128 -	Draft Email - An email discussing the items needed to include
ETH.MESH.04097131	into the draft of a piece of work
ETH.MESH.01208013 -	
ETH.MESH.01208038 and	Results +M Email - An email that discusses the summary of
Google Translate page	the results of a study
	Methodology to Prevent Mesh Torsion during Vaginal
ETH.MESH.02011262 -	Mesh Placement Email - An email that includes notes on the
ETH.MESH.02011267	sheath invention
ETIL MECIL 00504500	Our conversation to day Empil. An annell discussion about
ETH.MESH.00584592 - ETH.MESH.00584593	Our conversation today Email - An email discussing about
ETH.IMESH.00364393	potential options about the Anterior TVM project <b>TVM: First training: key learnings Email</b> - An email that
ETH.MESH.02282833 -	discussed the key points that will be analyzed and action items
ETH.MESH.02282834	made to address them.
2111111201110220201	mado to address trierin
	Project MINT/TVM group Email - An email discussing how to
ETH.MESH.03920748 -	handle the group in order to meet their needs and get done
ETH.MESH.03920749	what they wanted to get done
	PROLIFT Ordering lift Email - An email that discusses lifting
ETH.MESH.00132906 -	the restriction of restricting the ability of ordering from HCS to
ETH.MESH.00132907	ONLY those hospitals that had trained physicians.
ETIL MEOU 44000405	Prolift - A memo that discusses Prolift in detail including the
ETH.MESH.11630125 -	different stages, history, contradictions and product
ETH.MESH.11360130	characteristics
ETH.MESH.03736451 - ETH.MESH.03736452	Complaint - A complaint form about Gynecare Prolift
L 11 1.1VILO1 1.03/ 3040Z	Ouriplant - A complaint form about Gynecale Floint

	CYNECADE DOOLIET Dalvia Floor Banair Systems Forums
	GYNECARE PROLIFT Pelvic Floor Repair Systems Forums and Round Table Summary Powerpoint Presentation- A
	powerpoint that discusses the pre-op considerations, intra op
ETH.MESH.07346252 -	
ETH.MESH.07346252	considerations, post op considerations, management of complications and tips and tricks of the device
ETH.IMESH.07340232	complications and tips and theks of the device
	Notes from Meeting with Dr. V Lucente and Dr. M Murphy
ETH.MESH.01782783 -	(Allentown, PA) to discuss Prolift RCT - A memo including
ETH.MESH.01782785	notes from a meeting with two surgeons
ETH.MESH.00848180 -	
ETH.MESH.00848181	Posterior Prolift Email - An email discussing the use of
ETH.MESH.00850307 -	sutures during a posterior prolift
ETH.MESH.00850307 -	Hello from Tokyo Email - An email discussing various cases
ETH.IMESH.00030310	and various surgeons
ETH.MESH.00757565 -	Cynamach/Dalvia Floor Training Needs Email An amail
ETH.MESH.00757566	Gynemesh/Pelvic Floor Training Needs Email - An email discussing the educational training procedures
ETH.MESH.00737300 ETH.MESH.00848098 -	Prolift questions Email - An email discussing various
ETH.MESH.00848099	questions about Prolift
ETH.WESH.00848099	questions about Froint
	Export Opinions on the Use of Cymanau Bralift Complete
LIMECIA ETIL 04006740	Expert Opinions on the Use of Gynecare Prolift Complete,
HMESH_ETH_01896718 -  HMESH_ETH_01896729	Anterior, and Posterior Pelvic Floor Repair System - A
ETH.MESH.03932906 -	memo that discusses the expert opinion in depth about Prolift
ETH.MESH.03932900 -	<b>History of Prolift -</b> A memo that discusses in depth about the history of Prolift
ETH.MESH.06079837 -	Help Prolift Question Email - An email that discusses some
ETH.MESH.06079838	questions about prolift
ETH.IMESH.00079030	questions about profit
	Gynecare Prolift: Surgeon's Resource Monograph - A
	memo that gives a unique opportunity to the reader to have
	access to the experience of surgeons from around the world
ETH.MESH.04041373 -	who have each performed the GYNECARE PROLIFT* Pelvic
ETH.MESH.04041413	Floor Repair System procedure in a large number of cases
	, teet teep am eyetem precedence as a tenge manner en encee
ETH.MESH.00841557 -	Meeting in Roma - Dr. D'Afiero (Naples, ITALY) Email - An
ETH.MESH.00841558	email that discusses a potential modified prolift procedure
ETH.MESH.03503019 -	Prolift question Email - An email discussing a Prolift
ETH.MESH.03503020	complaint
	1 27 2
ETH.MESH.02017051 -	Ethicon Prolift Physician IDI's - A memo that discusses
ETH.MESH.02017084	Prolift and all of its components in detail
ETH.MESH.00006345 -	F
ETH.MESH.00006347	TVM study Email - An email discussing the attached study
	1 2

ETH.MESH.03472803 -	
ETH.MESH.03472821	Prolift - A memo that discusses prolift and gynemesh in detail
	у полити
ETH.MESH.01239420 -	RAB - T-Pro redefinition Email - An email that discusses
ETH.MESH.01239424	different types of mesh and questions/answers about them
	Promisa Take Away Messages Email - An email discussing
ETH.MESH.07171404 -	important highlights of a meeting where promisa was
ETH.MESH.07171406	discussed
ETH.MESH.08174214 -	Tomorrow Email - An email discussing reviewing material
ETH.MESH.08174227	before a meeting
ETH.MESH.03977109 -	Pre-Vote Call/Leadership Team Email - An email discussing
ETH.MESH.03977112	possible adjustments to professional education and training
	TVT NOTEBOOK
ETH.MESH.12009069 -	1998 Project Proposal for TVT Improvement - Proposal to
ETH.MESH.12009070	improve the appearance, packaging, and design of TVT
	71 3 37
ETH.MESH.12009027 -	GyneMesh II New Mesh Design - Document discussing
ETH.MESH.12009035	design of new mesh for repair of prolapse
ETH.MESH.11283974 -	Reisebericht: TVT-Brainstorming (PD 98/5) - Email of
ETH.MESH.11283974	meeting notes on TVT patent and future improvements
	Development Strategy - Email outlining development strategy
ETH.MESH.12009276 -	for TVT which includes preparing prototypes for improving
ETH.MESH.12009277	polypropylene mesh and the introducer needle/needle
ETH.MESH.12009262 -	WG Strictly Confidential Marketing Requirements For TVT
ETH.MESH.12009262	Improvement Team - Email listing requirements for marketing
ETH.MESH.08167452 -	R: Prof. Klutke - Confidential - Emails discussing the
ETH.MESH.08167453	possibility of publishing Dr. Klutke's TVT explant technique
	To Donald Ostergard - Letter responding to Ostergard's
ETH.MESH.10181921 -	editorial comments on a manuscript referred to as the TVT
ETH.MESH.10181922	supplement in the International Urogynecology Journal
ETH.MESH.12002601 -	TVT Improvements - Email listing new ideas for TVT
ETH.MESH.12002601	improvement that were discussed at a meeting in Hamburg
	D. TVT Becommended on a factor of the second
	R: TVT Recommendations from Dr. Wang - Emails
LIMEOU ETH 00050040	discussing TVT improvements and the use of the technique of
HMESH_ETH_00958016 -	releasing the plastic sheath overlap prior to inserting TVT
HMESH_ETH_00958017	needles in Europe and the U.S.

	D. TVT C Drainet - Empile discussing the possible
HMESH ETH OOGEOOO	R: TVT-S Project - Emails discussing the possible
HMESH_ETH_00958098 -  HMESH_ETH_00958100	implementation of manufacturing TVT with a shortened plastic sheath containing a marker
HIMESH_ETH_00936100	Sheath Containing a marker
	FW: Particle Release Characteristics of Clear and Blue TVT
	Mesh - Emailed report and spreadsheet from a project titled
HMESH ETH 00958313 -	Comparison of Particle Characteristics of Clear and 50% Blue
HMESH_ETH_00958316	PROLENE Mesh of TVT Device
TIMESIT_ETIT_00930310	RE: TVT complications (an Prof. Hausler) - Emails
ETH.MESH.03911107 -	recounting Dr. Arnaud's conversation with Professor Hausler
ETH.MESH.03911108	on erosions due to TVT mesh
E111.WESI 1.003 1 1 100	High Level Follow Ups from Today's Meeting - Meeting
ETH.MESH.00858080 -	notes discussing production and marketing steps for the
ETH.MESH.00858081	implementation of TVT-O
ETTIMESTI.0000000T	implementation of 1 v 1 G
	TVT Clear and Blue Mesh Information - Emailed Corporate
	Product Characterization reports on elements of mesh
	production including knitting, scouring, and heat setting
ETH.MESH.01218429 -	processes for new construction and old construction
ETH.MESH.01218449	PROLENE mesh
E111:WESI1:01210443	I NOLLINE MESM
ETH.MESH.00584592 -	Fw: Our conversation today- Emails discussing design ideas
ETH.MESH.00584593	for the Anterior TVM project and the production of prototypes
211 mv201 m0000 1000	RE: Aug 11 program - Email of Dr. Aguirre's questions about
ETH.MESH.00864131 -	TVT-O following a lecture event and emails discussing how to
ETH.MESH.00864133	respond to him
	roopena to min
	FW: Prolene fraying and MDR reporting practice - Archived
HMESH ETH 02115988 -	email about the fracturing and breaking of the Prolene device
HMESH_ETH_02115988	being misrepresented as a fray
	<u> </u>
ETH.MESH.06212843 -	FW: Prolene fraying and MDR reporting practice - Emails
ETH.MESH.06212844	discussing whether or not to report Prolene fraying
ETH.MESH.00867529 -	
ETH.MESH.00867530	
and	RE: TVT-O - Emailed report and comments from Neuchatel on
ETH.MESH.06886761 -	the first manufactured TVT-O samples and emails discussing
ETH.MESH.06886767	the issues raised in the report
	· ·
	Mesh Fraying For TVT Devices - Memo from Dr. Weisberg
	addressing complaints of fraying mesh during placement of
ETH.MESH.00541379 -	TVT devices and explaining that fraying does not affect the
ETH.MESH.00541380	safety of the device
	•

	DE la catante 2 TVT Compleinte concerning allege du
ETILMENI 00000004	RE: Important: 2 TVT Complaints concerning allegedly
ETH.MESH.00863391 -	brittle mesh - Emails discussing complaints that mesh
ETH.MESH.00863393	particles fell off of TVT during the surgery
	Summary of a Confidential Meeting Concerning Potential
	Modifications of TVT-O - Letter from Professor Jean de Leval
ETH.MESH.02180759 -	of the University of Liege summarizing a meeting discussing
ETH.MESH.02180761	changes to the TVT-O design
	TVT Obturator PM - Powerpoint presentation on TVT-O
ETH.MESH.00523733 -	detailing surgical techniques, patient selection, clinical studies,
ETH.MESH.00523733	and sales strategies for the device
L 111.IVILSI 1.00323733	Updates on Continence Health - Emailed report summarizing
ETI   MEQL   0000 4007	1 .
ETH.MESH.00994927 -	a meeting between Ethicon and an agency on marketing
ETH.MESH.00994929	strategy for TVT
	RE: Surgeons really want to know the best way to code for
HMESH_ETH_01882900 -	<b>Prolift -</b> Emails discussing the standardization of insurance
HMESH_ETH_01882901	coding for Prolift and treatment of mesh erosion
	AW: Next Generation TVT SECUR - Emailed Invention
	Disclosure report for a NEW TVT-SECUR device designed to
ETH.MESH.06868209 -	further reduce the risk of bladder perforation and to reduce
ETH.MESH.06868227	vagina erosions
L111.WESI1.00000221	vagilla elosiolis
ETH.MESH.01822361 -	DELTAT SECUE Emails discussing reported TVT Secur
	RE: TVT SECUR - Emails discussing reported TVT-Secur
ETH.MESH.01822363	complaints about the fixation tip, bleeding, and tension
	EWHU Communication: TVT SECUR: What's New 11/2/06 -
ETH.MESH.07396540 -	Emailed report of Procedural Pearls and Frequently Asked
ETH.MESH.07396546	Questions for TVT-Secur, designated for internal use only
ETH.MESH.00998253 -	RE: GYNECARE TVT SECUR Brochure - Email regarding
ETH.MESH.00998257	changes in TVT-Secur sales aid and emailed copy of sales aid
	RE: NICE IP review on Single Incision Sub-urethral slings
	(TVT Secur) - Emails discussing NICE's Interventional
ETH.MESH.03922228 -	Procedure provisional recommendation on TVT-Secur in which
ETH.MESH.03922230	NICE restricts the use of TVT-Secur to clinical trials
L I I I.IVIL OI I.U33ZZZ3U	INIOF LESTINGS THE USE OF LALL-SECON TO CININGAL MAIS
	For PROLIFE . M. Ponietrotion. Family discussing a service
ETIL MEQUI OF COCACA	Fw: PROLIFT + M Registration: Emails discussing comments
ETH.MESH.05009194 -	allegedly made by Dr. Lucente about Prosima and TVT-Secur
ETH.MESH.05009196	and email discussing Prolift +M registration in Australia

ETH.MESH.04048515 - ETH.MESH.04048520	Meeting and Interview with Key Opinion Leader Carl Nilsson - Report transcribing meeting discussion about development of a Next Generation Mini-Sling
ETH.MESH.04092868 - ETH.MESH.04092869	#10100080654 and TVT IFUs - Email from Dr. Meng Chen recommending updating the IFU's for TVT, TVT-O, and TVT-Secur to reflect the manufacturer's current knowledge of adverse reactions
ETH.MESH.01202101 - ETH.MESH.01202103	RE: My Revised Write-up of the DeLeval and Waltregny Visit - Emails discussing summary of a meeting on TVT-O
ETH.MESH.04050265 - ETH.MESH.04050267	Summary of Meeting with Professor deLeval and Prof Waltregny - report summarizing questions discussed at meeting about the source of TVT-O pain and mini TVT-O
ETH.MESH.04094863 - ETH.MESH.04094864	RE: TVT IFUs on Tape Extrusion, Exposure and Erosion - Email from Dr. Chen recommending a more specific warning statement on TVT-A, TVT-O, and TVT-S IFUs articulating that transitory local irritation at the wound site and a transitory foreign body response to the tape may occur which could result in tape extrusion, tape erosion, fistula formation or inflammation and email setting up a meeting to discuss
ETH.MESH.09951087 - ETH.MESH.09951090	Things to Consider as We Assess Next Steps for a Next Generation Sling: Emailed outline of discussions on possibilities of Professor DeLeval's Mini-me sling, a next generation TVT-Secur, and a next generation Scion
ETH.MESH.02596622 - ETH.MESH.02596623	FW: PROSIMA Take Away Messages - Emails detailing technical, financial, and organizational concerns about introducing PROSIMA to the market
ETH.MESH.00174793 - ETH.MESH.00174809	RE: TVT Integrity Selling Brochure - Emailed draft of Incontinence Selling Guide for TVT, TVT-O, and TVT-Secur detailing how to conduct selling interviews and handle common objections
ETH.MESH.08581280 - ETH.MESH.08581282	Equivalence Supported by Pre-clinical Performance Studies - Report on cadaver study in which side by side anatomical observations of TVT-O and the proposed TVT- Abbrevo were performed

	RE: Product Complaint CC1007005-Taiwan - Emails
ETH.MESH.13204508 -	-
	discussing complaints in which tiny mesh pieces were found in
ETH.MESH.13204521	the unopened tyvek TVT-O box and pictures of mesh pieces
	Ethicon Products Classified as Microporous, Medium, and
	Macroporous - Chart identifying TVT slings as microporous,
ETH.MESH.05479535 -	Gynemesh, Prosima, and Prolift as medium, and Gynemesh
ETH.MESH.05479535	+M and Prolift +M as macroporous
ETH.MESH.11353422 -	Risk Assessment Summary for Products in Gynecare TVT-
ETH.MESH.11353439	Secur System - Risk assessment report for TVT-Secur
	RE: Re Ultrasonic Slitting of Prolene Mesh for TVT - Email
ETH.MESH.00584811 -	from Gene Kammerer answering questions on the ultrasonic
ETH.MESH.00584813	cutting process for TVT.
211111112011100001010	Culturing process for 1 1 1 1
ETH.MESH.06857886 -	Mechanical vs. "Machine"-cut Mesh - Powerpoint on
ETH.MESH.06857886	mechanical vs. ultra-sonic/laser cut mesh
211111112011100001000	International verticinal certification out the certification
	Project TVT Laser Cut Mesh Design History File - Review
	evaluating the responses from surgeons in France who
ETH.MESH.01219542 -	evaluated the Laser Cut Mesh in comparison to the Mechanical
ETH.MESH.01219548	·
ETH.IVIESH.01219346	Cut Mesh for TVT products.
	RE: Particle Loss on TVT - Emails discussing TVT particle
ET.   1450    0.404000	loss and Performance Evaluation Test Report evaluating the
ETH.MESH.01219629 -	amount of particle loss in laser cut and mechanical cut TVT
ETH.MESH.01219646	Prolene mesh
	TR: First Human Use - Surgeon Preference Questionnaire -
	Emails discussing changes to a surgeon questionnaire part of
	the First Human Use protocol and the questionnaire titled: An
	Evaluation of the Application of the GYNECARE TVT
	Obturator*
ETH.MESH.01220216 -	System Tension -free Support for Incontinence with Laser Cut
ETH.MESH.01220230	Mesh
	Photographs of LCM vs MCM - Emailed Powerpoint of
ETH.MESH.08334244 -	photographs comparing laser cut mesh with mechanical cut
ETH.MESH.08334245	mesh after 50% elongation
	RE: Conversion to Laser Cut TVT - Emails discussing
ETH.MESH.16416002 -	concerns about transitioning from mechanical cut to laser cut
ETH.MESH.16416004	mesh
	1

	04/15/08 Trip Notes - Notes from TVT-O cadaver surgeries,
ETH.MESH.02090196 -	anatomical dissection, and discussions about TVT-O, TVT, and
ETH.MESH.02090190	TVT-Secur with Drs. de Leval and Waltregny
L 111.WL311.02090209	<u> </u>
ETIL MEQUI 04000550	Notes on Liege Visit - Notes from meeting with Dr. deLeval
ETH.MESH.01238552 -	and Dr. Waltregny about suggested modifications for medium
ETH.MESH.01238553	TVT-O
	FW MEMO as TVT O Bastislas Basti Oleanna Latter Facili
	FW: MEMO re TVT-O Particles: Draft Closure Letter - Email
	discussing the remote possibility of adverse consequences of
HMESH_ETH_08484481 -	tiny mesh particles in TVT-O packaging and closure letter
HMESH_ETH_08484482	responding to complaints
ETIL NEOU 200 44000	
ETH.MESH.03941623 -	TVT ABBREVO ALERT - Email in which Dr. de Leval
ETH.MESH.03941623 and	attributes four recent TVT-Abbrevo erosions in his patients to
Translation by CVA	the use of laser-cut mesh and requests an inquiry
ETH.MESH.11283949-	WG: Trip reportMeeting with Dr. Ulstem - Emailed notes
ETH.MESH.11283951	from a Stockholm Trip Report
	Dr Lucente/TVT Procedure Improvements/Prevention of
	Overstretching - Email from Dr. Arnaud directing Dr. Saller to
ETH.MESH.03915380-	begin a project to improve design of TVT and standardize the
ETH.MESH.03915380	TVT procedure
	RE: TVT-O FEEDBACK FROM SURVEY - Attention
ETH.MESH.03620573-	Required - Emails discussing results from surveys from TVT-O
ETH.MESH.03620575	Telesurgery Program
	Re: Ongoing TVT-O Action Items - Emails discussing issues
ETH.MESH.00864503-	with tensioning of TVT, sheath removal, and different
ETH.MESH.00864507	techniques used
	·
	Updated Trainers Guide - Email of updated guide for
ETH.MESH.00056921-	facilitators conducting training for TVT Secur and copy of guide
ETH.MESH.00056953	titled Gynecare TVT Secur Trainers Guide
	,
ETH.MESH.03921637-	Fw: TVT SECUR Units sold 21 November - Emails
ETH.MESH.03921640	discussing reasons for the decrease in sales of TVT Secur
	TVT Email - An email with an attached powerpoint discussing
ETH.MESH.01758770	TVT Secur
ETH.MESH.06927248-	Scion Email - An email discussing documents that define
ETH.MESH.06927249	SUI/SIS space
ETH.MESH.00281482-	Promisa Feedback Email - An email discussing the feedback
ETH.MESH.00281484	from Promisa from a previous meeting
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	Australia update and telephone call with Prof Frazer Email -
ETILMECI 00207000	An email that discusses updates from a professor, IFU
ETH.MESH.00327060	information and complaints
ET. 1 1 1 2 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2	TVT WORLD AE Report Email - AN email that discusses
ETH.MESH.03208548-	erosion rates and investigators
ETH.MESH.03208549	
	Ethicon Women's Health and Urology Brand Equity Study
	Powerpoint Presentation - A powerpoint that discusses an
ETH.MESH.03643186	equity study
ETH.MESH.03923121-	Trip to Israel Email - An email that discusses the attached
ETH.MESH.03923122	TVTS complication summary
	Background Information GYNECARE Pelvic Floor Repair
	Products and GYNECARE TVT Secure - An email that
	discusses the attached Background Information GYNECARE
	Pelvic Floor Repair Products and GYNECARE TVT Secure
ETH.MESH.05600916-	information
ETH.MESH.05600923	
	TVT WORLD AE Report Email - An email that has the TVT
ETH.MESH.07181044	WORLD AE Report attached
E111.WESI1.07 101044	WORLD AL Report attached
ETH.MESH.09951746-	MiniMe discussion at the board meeting Email - An email
ETH.MESH.09951748	that discusses the attached information on MiniMe
E111:WES11:09951740	
ETH.MESH.00864131-	RE: Aug 11 Program - Email of Dr. Aguirre's questions about
ETH.MESH.00864133	TVT-O following a lecture event and emails discussing how to
ETH.WESH.00604133	respond to him
	De Aguirre Internel Hee Only Empile discussing the
ETILMECH 0000000	Re: Aguirre - Internal Use Only - Emails discussing the
ETH.MESH.08020093-	market for Prosima, Dr. Aguirre's contract revision, his
ETH.MESH.08020094	complaints about Prosima, and his use of Elevate
	DE. Aver 44 Drograms. Exercise discussion Dr. Dograms le churc
ETIL MECLI 44 440000	RE: Aug 11 Program - Emails discussing Dr. Rogers lecture,
ETH.MESH.11449230-	Dr. Aguirre's questions about TVT-O and why it would be better
ETH.MESH.11449232	than TVT, and the draft of a response to Dr. Aguirre
	DE: Oak adula fan De Millandskit ta Dansson - Englis
	RE: Schedule for Dr. Miller visit to Denver - Emails
ETIL MEOUL 44 400 450	discussing Dr. Aguirre's surgical schedule, Dr. Miller's
ETH.MESH.11468459-	attendance at several cases, and a case of Gynemesh removal
ETH.MESH.11468461	due to exposed mesh and bunching
	DE Casa The Latest Flores - Free No. Proceeds - D
	RE: OscarThe Latest Fiasco - Emails discussing Dr.
	Aguirre's frustration with Dr. Keil's involvement with Gynecare
ETH.MESH.11474337	and Dr. Aguirre's vs. Dr. Keil's worth in dollars to Ethicon

	Oscar The Plan - Email detailing justification for keeping
	Dr. Aguirre as a preceptor and justification for using Dr. Keil as
	a Key Opinion Leader and discussing best response to Dr.
ETH.MESH.11474341	Aguirre's frustration
	FW: LA Speaker Event - Emails discussing Dr. Aguirre's
	upcoming participation in Gynemesh PS preceptorship in
	Mexico, upcoming UCSD TVT-O training, Dr. Aguirre's
ETH.MESH.11474393-	participation in an AMS study, and his frustration with
ETH.MESH.11474397	Gynecare
	RE: Gynecare TVT Training, Remainder 2004 - Emails with
	Dr. Aguirre discussing professional education events, TVT-O
ETIL MEQUI 400 40000	training, Gynecare and competitor company clinical trials, and
ETH.MESH.19348368-	email about Gynecare's contract with him and use of him as
ETH.MESH.19348372	preceptor
ETI I MECI I 402 46602	Re: Thank you - Emails discussing choice of doctors to target
ETH.MESH.19346603-	for Prolift training, upcoming TVT-O training, and late night out
ETH.MESH.19346604	with Dr. Aguirre
	Patricia Hojnoski Deposition (no exhibits) - 04-16-13
	(
	Patricia Hojnoski Deposition (no exhibits) - 04-17-13
	Ramy Mahmoud, M.D. Deposition (no exhibits) - 07-15-13
	Ramy Mahmoud, M.D. Deposition (no exhibits) - 07-16-13
	Aran Maree, M.D. Deposition (no exhibits) - 07-22-13
	Aran Maree, M.D. Deposition (no exhibits) - 07-23-13
ETH.MESH.03910418 -	Triair Marce, M.D. Deposition (no exhibits) 07 20 10
ETH.MESH.03910421	RE: Mini TVT - mesh adjustment
ETH.MESH.01037447 -	,
ETH.MESH.01037455	Clinical Expert Opinion TVT SecurDraft1.doc
ETH.MESH.03906525 -	
ETH.MESH.03906525	Graft No Graft BRUSSELS.ppt
HMESH_ETH_01800994 -	
HMESH_ETH_01800997	FW: Preclinical Contraction Model
ETH.MESH.00329316 -	
ETH.MESH.00329317	TVT-S Complaint review
ETH.MESH.00519476 -	
ETH.MESH.00519481	RE: TVT-S Cookbooks
ETH.MESH.01784428 -	
ETH.MESH.01784435	RE: TVT-S Cookbooks

ETH.MESH.00324086 -	
ETH.MESH.00324088	RE: Complaints TVT Secur - Germany
ETH.MESH.00330141 -	
ETH.MESH.00330141	TVT-S
ETH.MESH.01782867 -	
ETH.MESH.01782867	Tucson Mesh Shrinkage talk.ppt
ETH.MESH.00329557 -	<u> </u>
ETH.MESH.00329558	RE: user recommendation for TVT Secur
ETH.MESH.03922618 -	
ETH.MESH.03922618	Conf call tomorrow
ETH.MESH.05920616 -	
ETH.MESH.05920617	Defining light weight mesh
ETH.MESH.02105223 -	Harel Incontinence Update TVT & Bulkamid incl EMEA
ETH.MESH.02105223	Strategy.ppt
ETH.MESH.00858636 -	
ETH.MESH.00858641	Lessons_Learned TVT Secur 101507.doc
ETH.MESH.00642325 -	
ETH.MESH.00642331	RE: TVT O versus TVT Secur efficacy and safety rates
ETH.MESH.03845446 -	
ETH.MESH.03845450	Re: SECUR Update presented in at WW Mktg Meeting
ETH.MESH.04126728 -	
ETH.MESH.04126730	GYNECARE TVT SECUR.doc
ETH.MESH.00823421 -	
ETH.MESH.00823422	Australian SECUR Telecon 31 Oct 2007.doc
ETH.MESH.00312179 -	RE: Meeting with the Australian Regulator to discuss TVT
ETH.MESH.00312182	Secur performance
ETH.MESH.06051144 -	
ETH.MESH.06051146	RE: Australia update and telephone call with Prof Frazer
ETH.MESH.00874445 -	
ETH.MESH.00874445	TVT-S QB.ppt
ETH.MESH.06051286 -	
ETH.MESH.06051286	Operations Integrations
ETH.MESH.04127062 -	
ETH.MESH.04127063	FW: TGA update for TVT Secur
ETH.MESH.00836975 -	
ETH.MESH.00836977	Re: Mesh Shrinkage
ETH.MESH.04127331 -	
ETH.MESH.04127331	TVT Secur - re-training
ETH.MESH.00857704 -	
ETH.MESH.00857705	AW: T-PRO_TPP.ppt
ETH.MESH.04474756 -	
ETH.MESH.04474760	Att 3 Hota Secur RCT.pdf

ETH.MESH.01037447- ETH.MESH.01037455	Mostafa, A., Lim, C., Hopper, L., Madhuvrata, P., Abdel-Fattah, M., "Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: An Updated Systematic Review and Meta-Analysis of Effectiveness and Complications, European Urology 65 (2014) 402-427.  Gynecare - Clinical Expert Report (Gynecare TVT Secur System), August 23, 2005  Mulberry update Email - An email that discusses the updates
ETH.MESH.00260591	for the Mulberry Project
ETH.MESH.02180737	Project Mulberry Email - An email that discusses that Project Mulberry is critical to GYNECARE's success in the incontinence marketplace
ETH.MESH.06892171	TVT-O recognition Submission Email - An email that discusses the Submission of award proposal to HR
ETH.MESH.18726846	Status Report - A report on sales through October 1998
ETH.MESH.18727052	TVT Professional Education Program Memo - A memo discussing the March 13, 1999 Cadaver Lab in Savannah, GA
ETH.MESH.18727064	TVT Professional Education Program Agenda - An agenda including Interactive Telesurgery
ETH.MESH.11433727	<b>TVT Training Letter</b> - A letter responding to inquiries about TVT training
ETH.MESH.03662694	Products and Technologies for Incontinence and Pelvic Floor Defects Article - An article focusing on biological materials
ETH.MESH.11433817	<b>TVT Training Schedule</b> - Schedule showing available course dates and locations
ETH.MESH.10211669	Weekly Sales Report - A report for week ending January 2000
ETH.MESH.10211668	Weekly Sales Report Email - Email with report attachment
ETH.MESH.11829588	Gynecare Monthly Status Report Email - Email discussing the Gynecare products sales results
ETH.MESH.10217906	8/25 - TVT Update Email - An email enclosing the most updated TVT Training spreadsheets.

ETH.MESH.02095329	Northside Hospital Institutional Review Board Application - An Application for approval of proposed research
ETH.MESH.07728935	Gynecare March Status Report Email - Am email that discusses sales results through March, 2001
HMESH_ETH_00965818	Clinician Focus Group for Vypro Email - An email that discusses enlisting US clinicians to participate in a focus group
ETH.MESH.03716521	Pelvic Floor Conference Email - An email discussing conference meeting logistics
HMESH_ETH_00968253	Pelvic Floor Mesh Expert Panel Invitation Email - An email discussing the agenda for the proposed panel meeting
ETH.MESH.02089392	Scientific Advisory Panel on Pelvic Floor Repair Minutes - The minutes of a meeting discussing product development approach
ETH.MESH.05643781	<b>Gynemesh Vypro Notes</b> - Some notes on the June 22, 2001 Chicago Expert Panel
HMESH_ETH_00131657	Scientific Advisory Panel on Pelvic Floor Repair Minutes - The minutes of a meeting discussing product development approach
ETH.MESH.11463188	Las Vegas? Email - Am email discussing upcoming TVT cadaver course
ETH.MESH.11463193	Re: Las Vegas Course Email - An email discussing availability to teach the Las Vegas course
ETH.MESH.10218231	Preceptor & Procedure Specialist TVT Inventory List Email An email with attachment containing list of preceptors
ETH.MESH.10218233	<b>Preceptor Inventory List</b> - A list containing preceptors by specialty, product, and sales Rep.
HMESH_ETH_00134526	Transcript email - An email with the transcript from the Pelvic Floor meeting in Chicago attached
HMESH_ETH_00134527	Gynecare, Inc. Pelvic Floor Advisory Panel transcript
ETH.MESH.11462397	IMPORTANT - Push to maximize TVT Preceptorships Email - An email discussing maximizing the use of TVT National & Local Preceptorships.
ETH.MESH.11463220	Nov. TVT Course Email - An email discussing logistics for upcoming course
ETH.MESH.10218339	Website Resource Email - An email discussing usefulness of Dr. Miklos's website

ETH.MESH.11463253	Checking in Email - An email discussing upcoming TVT Cadaver course logistics
	TVT Professional Education Program with Cadaver Lab
ETH.MESH.11463254	Agenda
	Eastern Regional Cadaver Lab - December 15th in
ETH.MESH.10220214	Savannah, GA Email - An email with participant's details of
L 111.IVIL OI 1. 10220214	cadaver lab attached
	Cadaver lab attached
ETH.MESH.10220216	Eastern Regional TVT Professional Education Program
	with Cadaver Lab Agenda
ETH.MESH.10217467	Miklos TVT Dec. 11th email - An email with travel information
ETH.WESH.10217407	on Dr. Miklos' course
ETH.MESH.10217468	TVT Schedule - An itinerary for Dr. John Miklos preceptorship
	Transmitted of the control of the co
ETH.MESH.10217334	RE: TVT-A Pilot Launch Email - An email requesting input in
ETH.MESH.10217334	
	the GYNECARE TVT with abdominal guides, launch
ETH.MESH.03732403	READ THIS ONE: TVT-AA Study Docs Email - An email with
E 111.WEG11.007 02400	TVT study guides attached
ETIL MECIL 00004426	TVT Preceptorship Program letter - A letter discussing
ETH.MESH.00001136	available training slots
	Investigator & Sub-Investigator(s)
ETH.MESH.03732361	CVs/ Licenses - Dr. Miklos' CV
	OVS/ LICENSES - DI. IVIRIOS OV
ETIL MECULA 0000754	Drete and 2004 042 letter. A letter analoging submission
ETH.MESH.16009754	Protocol 2001-012 letter - A letter enclosing submission
	documents for Gynecare TVT with Abdominal Guides Protocol
ETH.MESH.03732417	GYNECARE TVT with abdominal guides case report cover
E111.WEG11.03732417	letter - No attachment attached
ETH.MESH.00401304	Protocol #: 2001-012 letter - A letter of introduction as the
	independent review board (IRB) for the research protocol
	Protocol Approval - An Approval for the Clinical Assessment
ETH.MESH.00401306	of Patients Undergoing GYNECARE TVT with
	abdominal guides for the Treatment of Stress Urinary
	Incontinence Protocol
	Consent Form - A form for GYNECARE TVT with abdominal
ETH.MESH.03732388	
	guides for the
	Treatment of Stress Urinary Incontinence Protocol
ETH.MESH.03732424	Site Initiation Conference Call Fax - A fax with site initiation
	conference call agenda attached
ETH.MESH.03732425	Site Initiation Conference Call Agenda - Agenda items for
	Protocol #2001-12
	Preceptorship Letter - Letter providing details of upcoming
ETH.MESH.00001134	preceptorship courses
	Thierehrolouih compes

ETH.MESH.03732419   Sit	te Initiation Report Form
ETH.MESH.10219036	E: Local and regional conferences Email - An email
dis	scussing upcoming conferences
ETH.MESH.10219052 RE	E: Updated Lead list for TVT
Pr	otocol #2001 -012 -A Clinical Assessment of Patients
Ur	ndergoing GYNECARE TVT with
ETH.MESH.03732412 ab	dominal guides for the Treatment of Stress Urinary
	continence Letter - Letter enclosing Study
Ma	anual/Investigator's File
	Clinical Assessment of Patients Undergoing GYNECARE
	/T Letter - A letter noting changes to informed consent form
	onsent Form - A form for GYNECARE TVT with abdominal
	ides for the
l re	eatment of Stress Urinary Incontinence Protocol
ETH.MESH.10219527	V: Email - An email with a message stating "Approved"
ETH.MESH.10219258	/T Nat' I Preceptorship Form - Pre-Event Registration Form
	E: GYNECARE TVT with Abdominal Guides - Enrollment
	odate Email - An email discussing study inputs
TETH M/ESH 100717568	E: Tommy LyonsNovasure Email - An email discussing
CO	mpetition ads
	ear Doctor: Letter - A generic letter discussing available
	ining opportunities for TVT tension-free Support for
	continence.
	e: Protocol 2001 -012 - Enrollment fax - A fax discussing
en	d of protocol enrolment
ETH.MESH.03605309	onsultant Invoice - Invoice for Melvyn A. Anhalt, M.D.
	onsultant invoice - invoice for iviely if A. Armait, Ivi.b.
ETH.MESH.10220545 Fa	culty dinner July 19, 2002 Email - Email discussing
	elcome reception for TVT cadaver lab participants
, we	biodine reception for 1 v 1 oddaver lab participants
Gr	assroots Outreach Updates : THERMACHOICE, TVT and
1ETH MESH 10658645	TERGEL - A memo discussing outreach efforts with
	spitals in each market
FV	V: GYNECARE TVT LAB Email - Email with details of
1E LH MESH 03624015	nfirmation numbers
ETH.MESH.10220564 Ag	genda for TVT cadaver lab July 20, 2002 Email - Am email
	ating the final agenda for cadaver lab
	onsultant Invoice - Invoice for Atlanta Medical Research,
L.L	L.C.

ETH.MESH.05299785	A Clinical Assessment of Patients Treated for Stress Urinary
	Incontinence using GYNECARE TVT with
	abdominal guides Power Point
	Product Complaint Checklist Form - A form for Pubourethral
ETH.MESH.12931117	sling procedure using GYNECARE TVT with abdominal guides
	complaints.
ETH.MESH.10219595	Dr. Miklos interview tomorrow email - email discussing
L 111.WES11.10219393	Miklos' media interview
ETH.MESH.0749789	Dr. Milded TVT Dresentenskip. Event Colondar antw
	Dr. Miklos' TVT Preceptorship - Event Calendar entry
ETH.MESH.0810755	FW: Dr. Swanson Email - An email discussing sales rep.
ETILMENI 20450040	position change
ETH.MESH.22453949	Synthetic Sling Online Activity Powerpoint
ETH.MESH.11525565	"who's who list Email - A cover email referencing faculty list enclosed
ETH MESH 1152566	Brief "Who's Who" list of TVT Faculty
ETH.MESH.1152566	Brief Wrio's Wrio list of TVT Faculty
ETH.MESH.00030332	FW: Lap Burch vs. TVT Email - Email discussing
ETTWEST1.00030332	material/review for the West Coast team.
	material/review for the vvest edust team.
ETH.MESH.00030340	Patients at risk for intrinsic sphincter deficiency article
ETH.MESH.11468051	FW: Possible dates for lab - Dr. Albo email - Email
	discussing Dr. Albo's Somerville availability dates
ETI I MEQUI 40000074	FW: Prof Ed forms email - Email discussing amendments to
ETH.MESH.10220674	Event Request Form
ETH.MESH.10220675	Event Request Form
ETH.MESH.10220676	Event Request Form
ETH MESH 02277604	FW: Pelvic Floor VOC email - Email about plans to get
ETH.MESH.02277691	together with Scott to discuss ATHOS VOC-
ETILMENI 40057500	take a look at this email - An email with a slide presentation
ETH.MESH.19257583	that Miklos proposes to do attached
ETH.MESH.19257584	Clinical Concept Overview powerpoint attachment
ETH.MESH.00260591	FW: Mulberry update email - An email discussing planning of
	implementation of Post market introduction studies in US
ETH.MESH.00260593	RE: Mulberry update email - An email discussing including
	Post market introduction studies in US in budget
ETILMECI 00000554	EW. Mulberry undete email. An email discussing planning of
ETH.MESH.00260551	FW: Mulberry update email - An email discussing planning of
	implementation of Post market introduction studies in US

ETH.MESH.02270685	RE: New Products for GYNECARE email - An email discussing attendance for the Somerville cadaver lab
ETH.MESH.02270927	Miklos, Kohli, and Garely for May 9th Lab email - An email discussing confirmation of attendees for lab
ETH.MESH.22461493	ARROWHEAD Campaign Agenda - An agenda discussing strategies for the competition
ETH.MESH.03620113	Consulting Agreement letter - Dr. Miklos' contract agreement terms
ETH.MESH.0030099	<b>FW: TVT letter to editor email</b> - An email discussing letter on TVT Outcomes
ETH.MESH.03919284	TVM- US Clinical Investigators email - An email discussing John Miklos and Kohli's interest in TVM.
ETH.MESH.02277699	RE: TVM- US Clinical Investigators email - An email discussing physician selection
ETH.MESH.02186825	ATHOS VOC Feedback letter - A letter discussing a survey on physicians practices for pelvic floor repair and their usage of suture and needles during this repair.
ETH.MESH.02277701	RE: TVM and Athos surgeon selection email - An email discussing Miklos and Garely ongoing participation in the project
ETH.MESH.02277704	RE: Feedback from Dr. Kohli email - An email - An email regarding surgeon selection and time constraints
ETH.MESH.02277712	RE: TVM, Athos, Porthos and other PF communications email - An email discussing concerns with the surgeon selection criteria.
ETH.MESH.02277716	RE: TVM, Athos, Porthos and other PF communications email - An email discussing issues with the surgeon selection criteria.
ETH.MESH.02277720	Dr. Kohli email - Email discussing Dr. Kohli's availability
ETH.MESH.04204492	FW: TVM Project with GYNECARE email - An email discussing Dr. Neeraj's availability
ETH.MESH.02270554	RE: July Trip email - An email discussing extending planned visit to Europe to see TVM cases by 1 additional day.
ETH.MESH.07628548	GYNECARE TVT* Advanced Users Forum Powerpoint
ETH.MESH.00569423	TVT Television Coverage on SUI transcript

ETH.MESH.00569432	11 Alive News Saturday Today broadcast transcript - Transcript on TVT Television Coverage on SUI
ETH.MESH.02270680	RE: Another Thing email - An email discussing the trip to France and incidental expenses
ETH.MESH.02268984	RE: Athos Clinical Protocol email - An email discussing observations from the trip
ETH.MESH.08838543	RE: Updated: Miklos email - An email discussing physician expenses
ETH.MESH.00030146	AUGS Convention Invitation letter email - An email with attached invitation
ETH.MESH.00030148	What's NEW in BLUE and easy to view? Letter - Invitation to AUGS Booth # 14-15
ETH.MESH.02095344	Consent To Participate In A Research Study - Draft Consent for Clinical Assessment of TVM Technique for Treatment of Genital Prolapse
ETH.MESH.05114429	RE: UTERINE HEALTH PRECEPTOR RATINGS email - An email discussing Uterine Health Contracts for 2004.
ETH.MESH.05114430	Excel sheet with list of preceptors and rating
ETH.MESH.16262560	Consulting Agreement - Dr. Aguirre contract terms
ETH.MESH.02269125	FW: US VOC email - Email discussing financing of January 26th Pelvic Floor meeting,
ETH.MESH.05745934	RE: Extra samples of TVM precut mesh email - Email discussing compliance with design controls and CE marking requirements.
ETH.MESH.02095435	TVM Pelvic Floor Project email - Email discussing update on the TVM Pelvic Floor Project.
ETH.MESH.02270972	FW: CV for Dr. Robinson & Feedback from Dr. Lucente to have Dr. R proctor himemail - Email discussing proctorship and hospital privileges
ETH.MESH.18726556	GYNECARE Incontinence & Pelvic Floor Summit - Draft agenda for Florida Summit
ETH.MESH.02270635	Re: Mint Raw Data Set email - Email about confidentiality of UK trip
ETH.MESH.03358755	RE: AMS Intexen update email - Email discussing discovery project for combining the Gynemesh PS with either the collagen GAG or the CBAT synthetic 35/65 foam.

ETH.MESH.03358748	RE: AMS Intexen update email - Email discussing issues with acquisition of material for discovery project
ETH.MESH.00623359	Powerpoint on Sales Plan Summary and Regional Analysis
ETH.MESH.00128276	RE: TVT docs Atlanta email - Email discussing setting up patient education events with Drs. Peacock and Roach.
ETH.MESH.00637878	FW: Miklos & Kohli Paper FYI email - Email discussing Drs. reputation in the medical community and AMS proposal to use them as investigators for the Intexen product
ETH.MESH.00637879	Article on Use of Synthetic Mesh and Donor Grafts in Gynecologic Surgery
ETH.MESH.02201463	RE: ICS / Paris - Gala Invitee List email - Email discussing logistics for gala event
ETH.MESH.08799571	"Wasn't sure if you have the updated" cover email (no message)
ETH.MESH.08799575	Powerpoint on TVT Influencers and competitor by region
HMESH_ETH_01870305	<b>FW: Perigee Newswire email</b> - Email discussing Dr. Miklos preceptoring for Gynemesh
ETH.MESH.11832732	RE: Top Opp's/Threats for TVT/TVT-O email - Email discussing strategies for threats by region
ETH.MESH.08716101	RE: Procedure email - Email discussing Miklos' website and a link to procedure at the Cleveland Clinic website
ETH.MESH.08716098	Images in a PPT pres - E-mail stating some images in the attached powerpoint were taken from Dr. Miklos's website and permission should probably be asked to use them.
ETH.MESH.08716098	Images in a PPT pres - Attached powerpoint with images taken from Dr. Miklos's website cited at the bottom of the slides.
ETH.MESH.03936121	TR: Miklos and Moore site internet - E-mail mostly in French. English portion discussing Drs. Miklos and Moore traveling to France to learn the "latest, safest and best innovations" in vaginal surgery.
ETH.MESH.05205229	TVM name being used by Miklos and Moore - E-mail discussing a Total Vaginal Mesh website constructed by Drs. Miklos and Moore.

ETH.MESH.0879658	TVTsling.com - E-mail discussing Dr. Miklos's use of the word "TVT" in regards to trademark and URL management.
HMESH_ETH_04944914	RE: Contract - E-mail stating contracts have been received and Miklos will be sending "something" soon.
ETH.MESH.08792939	FW: Recommendations for Non-Sales and Marketing Glabour Trip Award - E-mail stating that Miklos attended the hands on session with the pelvic model at ACOG event. Details rep "nominations for Galmour not related to sales or marketing."
ETH.MESH.11475478	RE: Capital equipment update in Orange County - E-mail detailing the status of Orange County. Notes "our mutual personal relationships with other Caldera preceptors" Drs. Garely and Miklos.
ETH.MESH.10211394	30 Day Update - E-mail attaching 30 day update.
ETH.MESH.10211395	30 Day Update - Update noting Drs. Miklos and Moore among key opinion leaders in Gynemesh.
ETH.MESH.06828981	RE: Screening assessment/Brystin - E-mail noting that Dr. Miklos has a patent for intra-urethral pressure monitor.
HMESH_ETH_01872594	FW: Miklos TOT - E-mail stating TOT article attached.
HMESH_ETH_01872595	<b>FW: Miklos TOT -</b> Transobturator Sling for Stress Incontinence (Subfascial Hammock) article attached from above e-mail. Drs. Miklos and Moore referenced throughout.
ETH.MESH.10224720	RE: Coming up to see you - E-mail stating that Miklos is doing training on the Caldera system sponsored by Select Surgical Technologies. Lucente notes a former resident is attending and is "disappointed."
ETH.MESH.10224730	AUGS posters - posters we need to check out - E-mail listing two posters that Miklos is authored on.
ETH.MESH.06079991	Info from Kajal from the Continence Health Brand Team - E-mail noting that a study shows Monarc subjective cure rate at 82.5%. Miklos among those who conducted the study.
ETH.MESH.17667274	FW: Info from Kajal from the Continence Health Brand Team - E-mail noting that a study shows Monarc subjective cure rate at 82.5%. Miklos among those who conducted the study.
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ETH.MESH.03908369	RE: Request to contribute to new Gynecare-supported Pelvic Floor Academy - E-mail stating Drs. Kohli and Miklos may not be good choices to contribute to Gynecare's new "Academy for the Study of Female Pelvic Floor Disorders."
ETH.MESH.02107681	AMS Afigee Perigee Procedure Video - E-mail stating Drs. Miklos and Moore have procedure videos of Apogee and Perigee on their website. To be used for competitive intelligence.
ETH.MESH.03605124	Certificate for TVT Secur training - Powerpoint with multiple certificates for training on TVT Secur for on 08/11/2006. Miklos among them.
ETH.MESH.00527044	RE: JJHCS# for docs trained on August 25th - E-mail discussing Kohli's observing cases with Dr. Miklos in Atlanta.
ETH.MESH.00847103	Contact - E-mail discussing a doctor having trouble with a patient with groin pain following a TVT-O. States Dr. Miklos was contacted regarding the etiology of this problem.
ETH.MESH.00847390	Case - E-mail discussing Dr. Vradelis having a problem with a patient having groin pain following a TVT-O. States Dr. Miklos was contacted regarding this problem.
ETH.MESH.06581293	Draft consulting agreement requisition form - Draft consulting agreement for Dr. Miklos dated 10/2006 - 02/2006.
ETH.MESH.13300571	<b>Keeton - file #10100023923 -</b> E-mail stating medical records review is attached.
ETH.MESH.13300572	<b>Keeton - file #10100023923 -</b> Attached medical records review. Dr. Miklos consult mentioned.
ETH.MESH.00455857	<b>Spreadsheet -</b> Spreadsheet listing preceptors. Dr. Miklos listed for course on 12/19/2006.
ETH.MESH.16462628	RE: Help Prolift question - E-mail asking whether Prolift or Apogee is better for repair. References an article written by Drs. Moore, Miklos, and Davilla showing 11% erosion in Apogee.
ETH.MESH.16462630	RE: Help Prolift Question - Attached article referenced in e- mail titled Restoration of Vaginal Apical and Posterior Wall Support with the Apogee System. Written by Drs. Davila, Beter, Moore, Del Rio, and Lukban.

ETH.MESH.06079837	RE: Help Prolift question - E-mail asking whether Prolift or Apogee is better for repair. References an article written by Drs. Moore, Miklos, and Davilla showing 11% erosion in Apogee.
ETH.MESH.00542685	FW: Dr. John Miklos - Action Required - E-mail requesting to invite Dr. Miklos to the next Congress in Buenos Aries (SOGIBA) and asking if he is a preceptor for TVT-S and Prolift. Zipfel responds that Miklos hasn't worked with them for a "number of years."
ETH.MESH.09453635	Lap prolift - E-mail sending Miklos's website for LSC. Also notes "back in the gynecare days, the Y-shaped piece of mesh he uses is a configuration that several doctors have asked for us to market for sacralcolp."
ETH.MESH.03908683	RE: Michel Cosson - E-mail discussing Dr. Cosson being an exclusive doctor for Ethicon. Notes that they don't want him to become "over exposed" and become a biased voice. Examples of other doctors at risk of this are Lucente, Miklos, Reid, Davilla, etc.
ETH.MESH.03927021	RE: Michel Cosson - E-mail reply to the above mostly in French. Reply translated to stating that the French are "a little different" than the Americans, and comparing Cosson to Miklos and Davilla is an "insult."
ETH.MESH.05104729	Fw: Argentina - E-mail discussing a trip by J&J Latin America to their national Ob/Gyn Congress. Mentions that Drs. Miklos and Moore will be presenting a talk titled "Minislings - the future?" and them presenting on anterior and posterior prolapse. Mentions that Miklos and Moore are "now the AMS marketing team."
ETH.MESH.00833467	Cath guide - E-mail that includes information from the "Miklos/Moore practice site" relating to TVT and the cath guide.
ETH.MESH.03971289	RE: 2008 Business plan powerpoint - E-mail stating the business plan assessment is attached.
ETH.MESH.03971291	RE: 2008 Business plan powerpoint - Attached powerpoint lists Miklos and Moore as an "anticipated challenge" with increased AMS presence. Other topics include: sales info, targets, current contracts, and keys to success.

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ETH.MESH.09195605	Article - Article titled "Mini-Sling - New Minimally Invasive One-Incision Sling for Treatment of Female Stress Urinary Incontinence" written by Drs. Moore and Miklos.
ETH.MESH.06928023	Miklos/Moore website - MiniArc - TVT Secur - E-mail sending a link showing Drs. Miklos and Moore talking about MiniArc and TVT Secur.
ETH.MESH.05429866	Profix 2-9 doc - E-mail with attachment.
ETH.MESH.05429867	Profix 2-9 doc - Attachment from above e-mail. Discusses "A SSL suspension using Profix and Pelvicol" performed by Drs. Mendelovici and Burrows. Dr. Miklos mentioned as thinking "Profix is better than Capio because it goes through the SSL instead of back around the SSL."
ETH.MESH.19706390	RE: Slings and things - E-mail in which Dr. Miklos clarifies some issues with a workshop titled "Hands-On Cadaver Course on Sling Placement for Treatment of GUSI." Issues include providing other slings, number of company reps available. Also includes Miklos's basic concept of teaching.  Mini Arc - E-mail discussing Mini Arc White Paper. Notes that
ETH.MESH.10051715	Drs. Miklos, Moore, Erikson, and Serels did the trial. Paper is attached.
ETH.MESH.10051716	Mini Arc - Mini Arc White Paper attached to above e-mail. Titled "MiniArc Single-Incision Sling System: A new minimally invasive single-incision sling for treatment of female SUI."
ETH.MESH.05771478	IC Cover Letter - E-mail discussing invitees to the Innovation Council. States one invitee is "linked to Miklos which has put a bad taste in many people's minds."
ETH.MESH.033252814	<b>RE: Lucente 3 year data -</b> E-mail looking for an article with the longest follow-up. Notes Miklos and Moore have reported up to 3 year data retrospectively.
ETH.MESH.08979271	RE: SurgeryU Live Event Surgeries - E-mail with information regarding a live surgery event with Drs. Miklos and Moore on 07/13/2010. Also includes biographical information.
ETH.MESH.03042339	RE: Question - E-mail looking for a way to "briefly explain what 'standardized trocar guided mesh kits' are." Reference to an article Drs. Miklos and Moore explained this.

ETH.MESH.10958477	Article - Article titled "To Mesh or Not to Mesh" moderated by Miklos, Lucente, and Park. Miklos does the "Welcome, Introductions and Course Overview" portion.
ETH.MESH.08413369	<b>RE: Mpathy mesh -</b> E-mail stating that doctors in the territories like the feel of Mpathy mesh more than Gynemesh. Drs. Miklos and Moore mentioned as some who feel this way.
ETH.MESH.16028234	RE: XXIV International Congress - E-mail discussion about International Congress meeting and attendees. Miklos and Moore mentioned as heavy AMS preceptors and to approach with caution.
ETH.MESH.16332702	Published online: Study elevate anterior/apical - E-mail with attached article published by Dr. Moore.
ETH.MESH.16332703	Published online: Study elevate anterior/apical - Attached article titled "Sincle-incision vaginal approach to treat cystocele and vault prolapse with an anterior wall mesh anchored apically to the sacrospinous ligaments" written by Drs. Moore, Mitchell, and Miklos.
ETH.MESH.10203239	<b>RE: SUFU -</b> E-mail from Lucente in which Miklos is cc'd on regarding the fact Miklos and Moore putting on a pelvic floor course in April.
ETH.MESH.05831909	CUDA US Launch Team - Team meeting minutes - E-mail discussing meeting minutes. Topics include: 510(k) clearance, LSC, contracting, price, competition, surgeon testimonials, and AMS doing "straight stick procedures." Miklos mentioned during AMS topic.
ETH.MESH.14414054	Copy review submission form - Form for "Gynecare TVT: Summit workshop presentation by Drs. Kohli and Miklos" for on 09/18/2002. Includes powerpoint.
ETH.MESH.10202187	RE: JnJ follow up per Dr. Miklos request - E-mail seeking presenter for MIGUS 2012 meeting. Dr. Moore looking for someone to present on Prolift.
ETH.MESH.10222380	FW: MIGUS 2012 opportunities - E-mail from Drs. Miklos and Moore seeking sponsorship for their Minimally Invasive Gynecology/Urology Surgical Symposium in 2012.

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ETH.MESH.10222382	FW: MIGUS 2012 opportunities - Attachment from above e-mail with the schedule for the MIGUS meeting.
ETH.MESH.08952097	FW: Event request form for MIGUS 2012 meeting - E-mail attaching information on the MIGUS meeting.
ETH.MESH.08952100	FW: Event request form for MIGUS 2012 meeting - Attachment from above e-mail with the schedule for the MIGUS meeting.
ETH.MESH.08952105	FW: Event request form for MIGUS 2012 meeting - Attachment from above e-mail listing the confirmed faculty for the MIGUS meeting.
ETH.MESH.08952109	FW: Event request form for MIGUS 2012 meeting - Attachment from above e-mail listing the overview, target audience, invited faculty, sponsorship opportunities, and educational grant opportunities for the MIGUS meeting.
ETH.MESH.11461673	Watch live Friday - E-mail announcing live surgical event with Drs. Miklos and Moore.
ETH.MESH.08578623	RE Have you seen this article - E-mail attached to the below e-mail. Hinoul mentioned Drs. Miklos and Moore "are not your average surgeons, as they consistently publish complication rates that are far below the accepted average."
ETH.MESH.08578264	RE: Have you seen this article - E-mail attaching an article mentioned at the MIGUS meeting. Mentions it states "good surgical technique reduces exposures."
ETH.MESH.08578627	RE: Have you seen this article - Article attached to above e-mail titled "Risk of mesh extrusion and other mesh-related complications after laparoscopic sacral colpopexy with or without concurrent laparoscopic-assisted vaginal hysterectomy: Experience of 402 patients" authored by Drs. Stepanian, Miklos Moore, and Mattox.
ETH.MESH.10182578	New Product Facts and Status - Document with various information on TVT. Dr. Miklos mentioned as a TVT Key Opinion Leader.
ETH.MESH.18830341	Chris Hawk 2 week field evaluation - E-mail attaching Chris Hawk's 2 week field evaluation.

ETH.MESH.18830342	Chris Hawk 2 week field evaluation - Attached field evaluation. Drs. Miklos and Moore mentioned during procedure, and Hawk having a chance to watch "world renowned surgeons" such as Dr. Miklos.
HMESH_ETH_00275235	<b>Memorandum - copy review submission compliance -</b> Copy review of "TVT tension-free vaginal tape - ACOG booth presentation." Powerpoint by Dr. Miklos included.
ETH.MESH.02491782	<b>Target sheet -</b> Very large document. Shows Dr. Miklos's information for "Gynecare TVT with abdominal guides - Data clarification form" and "clinical assessment" from 09/04/2002. [Pg 187-193]
ETH.MESH.11918826	<b>Spreadsheet -</b> Spreadsheet listing Dr. Miklos and highlighted in yellow. List shows information on contracts.
KE-001841189	Gynecare TVT - Powerpoint titled "Minimizing & Managing Intraoperative Complications: TVT Sling" by Dr. Miklos. Includes notes on slides.

## **EXHIBIT "B"**

## **REVIEW MATERIALS**

Bates Number	Description
	Liang, R., Abramowitch, S., Knight, K., Palcsey, S., et al., "Vaginal Degeneration Following Implantation of Synthetic Mesh with Increased Stiffness," BJOG, 2013 January; 120(2): 233-243.
	Meng Chen Deposition Designations with Exhibits (10/29/13) - 3321, 3322, 3324
	Meng Chen Deposition Designations with Exhibits (10/30/13) - 3326, 3328
	Gross Trial - Ciarrocca Testimony and Exhibits (1/15/13) - 354, 359, 370, 379, 382, 390, 401, 432, 454, 456, 472, 474, 485, 494, 498, 500, 501, 768, 967, 980, 1010, 1303, 1305, 1510, 1539, 1693, 1694, 1695, 1696, 1697, 1698, 1699, 1701, 1702, 1703, 1739
	Gross Trial - Hinoul Testimony and Exhibits (2/8/13) - P1593, D501, P785, P348, P1664, P1670, P616, P530, P591, P713, P693
	Gross Trial - Hinoul and Kammerer Testimony and Exhibits (1/16/13) - 1624, 1664, P629, 0344, 785, P1679, P756, 1258, 1670, P1143, P0750, 746, P28, 616
	Gross Trial - Arnaud and Henderson Testimony (2/1/13) - No Exhibits
	Batiste Trial - Hinoul Testimony and Exhibits (3/26/14) - D23202, D23501, P1406, J00079, 1404-R, 1271-R, 2312, 515, 1220, 1290, 2313, 180, 4272, 4164-R, 1987, D31111, 4169, 4083, 1164, 4099, 4100, 3460B, 2857, 4259, 2077, 279, 500, 573, 332, 4176, 528, 4216, 3946, 4218, 3352, 4037,3199, 942, 1011-R, 4271, 232, 464, 4130, 4220, 4105, 3948, 4204-C, 4203
ETH.MESH.09033951	Ethicon Credo - Credo of company
ETH.MESH.05924718- ETH.MESH.05924719	Ethicon Health Care Compliance Brochure - Brochure containing credo, summary of healthcare compliance, and highlights from guidelines for gifts to physicians from industry
ETH.MESH.11336216- ETH.MESH.11336225	Ten Year In Vivo Study: Scanning Electron and Light Microscopy Interim Report on Dog #1995 After 6 Years, 10.5 Month, SR #33788 - Letter summarizing conclusions about death of dog #1995 during study in which sutures were implanted and explanted
ETH.MESH.09264945- ETH.MESH.09264946	Prolene Mesh Re-Design Project - Letter summarizing proposed mesh re-design project goals and soliciting thoughts on regulatory strategy

RE: TVT recommendation from Dr. Alex Wang - Emails
discussing surgeon recommendations on TVT changes and
clinical significance of complaints of TVT tape deformity
Suture Spitting Literature - Emailed results of abstracts from
literature search around the topics of suture protrusion and
erosion
Dr. Alex Wang, TaiwanReports of tape rejection" with TVT -
Emails discussing Dr. Wang's report of a pattern of adverse
events in TVT cases which he considers potential rejections of
prolene mesh
RE: Mini TVT - Mesh Adjustment - Emails discussing Mini TVT
tensioning and whether or not there is a need for adjustment of
mesh or a possibility of over tightening it
Ethicon Surgeon Panel Meeting - Detailed notes and summaries
from multiple panel discussions and presentations on mesh -
both polypropylene and other - risks and complications, new
ideas, and design
Plaintiffs' Trial Exhibit P1739 (46 pp)
RE: D'Art: Risk Question - Emails discussing concerns about
reports of mesh retraction/shrinkage
Teporte of mean retraction/orininage
Top Ten Reason to Pursue GYNECARE TVT Obturator System -
PowerPoint listing reasons that TVT-O should be used
Ower out isting reasons that I v I -O should be used
RE: Observation of Tissue Tearing - Emails discussing tissue
tearing during strap placement in mesh procedures
RE: TVTO training Carmel Ramage - Emails discussing surgical
techniques diverging from the IFU for TVT-O during live surgery
training
RE: critical Q&A - Email response from Dr. Arnaud to request for
responses to customer questions on differences between
old/new Gynemesh and on erosion of the vagina with Gynemesh
Mesh research - Email from Dr. Kammerer with questions about
addressing the issue of scar reduction around implanted meshes
and the Ultra Pro material
TVT Tape - Letter of complaint from Dr. Eberhard re: crumbling
TVT tape
Dr. Hale and Prolift - Erosion Concern - Email of Dr. Hale's
concerns about grafts placed vaginally and erosions with
Gynemesh and emails discussing them

ETU MEQU 02200774	DE: D'Art Clinical Export Depart (CE Mark requirement) Empile
ETH.MESH.02280771- ETH.MESH.02280772	RE: D'Art Clinical Expert Report (CE Mark requirement) - Emails
ETH.WESH.02280772	discussing concerns about a Clinical Expert Report
	Confirmation of the Improved TVT-O (Mesh) Rationale (DRAFT)
ETILMECH 00442000	Email discussing current situation with customer complaints
ETH.MESH.00442080-	about TVT and presenting an analysis of the situation and
ETH.MESH.00442081	solutions
	Review of Surgical Techniques Using Mesh - PowerPoint
	presentation authored by Dr. Robinson on mesh techniques and
ETH.MESH.00752129 (35 PP)	issues
ETH.MESH.05795322-	RE: 01 PE results - REVISED - Emails discussing professional
ETH.MESH.05795324	education statistics and budgets
	Laser-cut Mesh - Email discussing from Product Director
ETH.MESH.00526473-	discussing a resolution on the use of Laser-Cut Mesh in TVT-
ETH.MESH.00526474	Secur
	Medical Director, Charlotte Owens - Handwritten phone notes,
	typed letter detailing complaints about Owens' leadership,
ETH.MESH.08473894-	illustrative emails referenced in letter, Owens' resignation letter,
ETH.MESH.08473974	HR exits and action forms, hiring forms
	Forgot - Forwarded email reporting patients unable to void after
ETH-80249	Prolift total procedures
ETH.MESH.06894281-	Re: MINT - Emails discussing excessive bleeding after a one-
ETH.MESH.06894283	step insertion technique for mesh straps during a posterior MINT
	Summary of Meeting at AAGL - Email discussing changes to
ETH.MESH.00133497-	adverse events section of IFU and summary of meeting on
ETH.MESH.00133499	voiding problems post Prolift procedure
	FW: TVT U Completion Report Version 3 - Emails discussing a
ETH.MESH.02135200-	study and papers comparing Laser Cut and Mechanical Cut
ETH.MESH.02135201	Mesh
	Re: Medical Device Reporting: Required Improvements to
	Investigations - Email and documents discussing investigation of
ETH.MESH.22129733-	MDR reportable complaints, complaint protocol, FDA
ETH.MESH.22129782	correspondence
ETH.MESH.00803777-	- Contraction -
ETH.MESH.00803777	Prolift Users Forum - Meeting minutes from Prolift forum
L 11 1.WLO1 1.000037 02	FW: Mesh Microns - Emails discussing pore size of Gynemesh
ETH-83454-ETH-83455	and Prolift
ETH.MESH.05454207-	
ETH.MESH.05454208	Photos Cadaver Lab - Emailed photo of mesh
	I notes cadaver Lab Emailed priote of mesh
ETH.MESH.00835753-	RE: Cosson - Email discussing doctors pressing for changes in
ETH.MESH.00835755	the Prolift kit and the possibility of making modifications to if
<u> Г. П. IVIЕЗП. 00033733</u>	The Front kit and the possibility of making modifications to II

	Factors Related to Mesh Shrinkage - PowerPoint discussing the
	shrinkage of mesh materials, Foreign Body Reaction, pore size,
ETH.MESH.01782867 (28 PP)	and literature on shrinkage
	RE: Technical information on Lightweight Mesh - Emails
HMESH_ETH_00109763-	requesting Ethicon formulate responses to a TYCO presentation
HMESH ETH 00109767	on polyester mesh
	Mechanical properties of synthetic implants used in the repair of
	prolapse and urinary incontinence in women: which is the ideal
	material? - Spreadsheet from a study detailing the pore size,
	· · · · · · · · · · · · · · · · · · ·
ETIL MECLI 00400000 ( 0 DD)	area weight, burst pressure, tensile strength etc. of different
ETH.MESH.02183202 ( 2 PP)	meshes
	Defining Light Weight Mesh - Email from WW Marketing Director
	detailing Ethicon's definition of lightweight mesh and asking
ETH.MESH.05920616-	questions about pore size, filament diameter, and absorbable
ETH.MESH.05920617	mesh
	RE: Light Weight Definition Core Team Minutes - Emails
HMESH_ETH_00080239-	discussing the development of a definition of Lightweight mesh
HMESH_ETH_00080243	and including future products in this definition
ETH.MESH.00922443-	RE: Bidirectional Elasticity Statement - Emails discussing edits
ETH.MESH.00922446	made to the Instructions For Use for Prolift +M
	Prospective TVM Studies - PowerPoint on TVM and Prolift
	studies in France and the U.S., failures and risk factors,
ETH.MESH.00821702 (26 PP)	prospective studies, and outcomes
	prospective stadios, and satesines
	RE: TVT O versus TVT Secur Efficacy and Safety Rates - Email
ETH.MESH.05208544-	detailing concerns about TVT-Secur's high failure rates, the
ETH.MESH.052005447	efficacy of its training program, and its lack of clinical data
L111.WE311.03200347	enicacy of its training program, and its lack of clinical data
	Mosting with the Australian Degulator to Discuss TVT Coour
ETI I MECI L 000074.44	Meeting with the Australian Regulator to Discuss TVT Secur
ETH.MESH.00827141-	Performance - Email brief on high TVT Secur failure rates and
ETH.MESH.00827143	scheduled meeting with Australian regulator
	Pelvic Organ Prolapse Repair: Lesson Learned from the
	PROLIFT Experience - Report by Dr. Arnaud detailing what
ETH.MESH.01218423-	surgeons like about Prolift and Prolift's issues during and after
ETH.MESH.01218424	the procedure
	Interim Report Mesh Explants Pelvic Floor Repair - Report on a
	study by Professor Klosterhalfen summarizing complications he
ETH.MESH.00006636	found following mesh implantation
	RE: Prosima - Please Don't Forward/Share - Emails discussing
ETH.MESH.03086214-	the analyses planned for Prosima data and concerns about the
ETH.MESH.03086219	commercial side of the company's involvement with research

ETH.MESH.03021946 (25 PP)	T-Pro Pipeline Leadership Team - PowerPoint on proposed T- Pro synthetic prosthesis to replace 'meshes' which are not developed specifically for pelvic reconstruction
ETH.MESH.02247342 (55 PP)	Historical Perspective The Journey from PROLIFT to PROLIFT+M - PowerPoint presenting history of Ethicon mesh products, insights on wound healing and tissue response, benefits of Prolift +M and comparison of it to competitor meshes
ETH.MESH.12003000- ETH.MESH.12003012	Literature Review and Analysis of Gynecare Prolift - Invoice billing for conducted analysis and literature review and report of analysis of literature on Prolift anatomy
ETH.MESH.00591127- ETH.MESH.00591128	RE: Registry for All! - Emails discussing making POP registry database available to the public and joking about failing mesh
ETH.MESH.02138454- ETH.MESH.02138455	RE: TVT Mesh Pore Size Measurement - Emails discussing a visual test method to measure porosity, but stating that there exists no written test method to measure pore size  Prolift +M - Pelvic Floor Meeting - PowerPoint about Prolift +M containing information on biocompatibility, mesh contraction, and
ETH.MESH.01264260 (33 PP)	tensile properties Plaintiffs' Trial Exhibit P1706 (55 PP)
ETH.MESH.00209295- ETH.MESH.00209299	RE: TVTO Mini IFU Rewrite - Emails discussing edits to the Instructions For Use for TVT-O mini, the importance of positioning, causes of leg pain after TVT-O procedure, and whether or not the TVT-O IFU needs to be rewritten
ETH.MESH.00851319- ETH.MESH.00851321	RE: PROSIMA Implant Dimensions - Emails discussing how to answer physician questions about PROSIMA dimensions, coverage of DeLancey levels, and erosion rates as compared to Prolift.
ETH.MESH.11205022- ETH.MESH.11205027	FW: CO-0022344 for your Review; Target Approval 04-12-2010 - Emails discussing a comparison of the Warning and Precaution statements for TVT, TVT-O, and TVT-A, contact of tape with the urethra, and pillowing of tissue through the pores of the mesh
ETH.MESH.01252509- ETH.MESH.01252512	RE: Review of Scion 2 Year Data - Emails discussing meeting scheduling to review Scion data and statement from Dr. Kirkemo that he hated obturator slings
ETH.MESH.02200585	Prolene - Notes on old weave and new weave mesh material, size, shape, and characteristics

ETIL MECIL 00044000	RE: CONFIDENTIAL: Background on Forthcoming NEJM Article
ETH.MESH.03641969-	Scheduled for May 12 - Emails discussing forthcoming study on
ETH.MESH.03641970	use of Prolift for POP, rates of adverse events, and media spin
	Bridging Fibrosis - PowerPoint slide discussing persistent
JJM.MESH.00441352	inflammatory reaction to heavyweight meshes
	Characteristics of Synthetic Materials Used in Prolapse and
	Incontinence Surgery (43 PP)
ETH.MESH.00863391-	Important: 2 TVT Complaints concerning allegedly brittle mesh
ETH.MESH.00863393	Email - An email discussing issues with TVT mesh
ETH.MESH.02180826-	Mesh Fraying: Dr EBERHARD letter Email - An email discussing
ETH.MESH.02180827	the issues of fraying mesh
ETH.MESH.02180828-	TVT Blue Fax - A fax discussing some issues that have come up
ETH.MESH.02180830	with TVT Blue
	TVT Tape - A memo discussing issues that have come up with
ETH.MESH.02180833	TVT Blue
ETH.MESH.00865322-	
ETH.MESH.00865323	Reminder on BLUE mesh Email - A email discussing complaints
ETH.MESH.01221055-	An independent biomechanical evaluation of commercially
ETH.MESH.01221058	available suburethral slings - An article discussing slings
	LCM Project, Photographs Comparing Laser Cut Mesh vs.
	Mechanical Cut Mesh
	Applied Science and Technology Analytical Characterization - A
ETH.MESH.12832662	memo that discusses the Prolene Soft Mesh Pore sizes
	Document 1 - Pore Size Measurement from Ethicon
	Document 2 - Pore Size Measurement from Ethicon
	Charlotte Owens Deposition - 09-12-12
	Plaintiffs'-3000 - Curriculum Vitae
	Plaintiffs'-3001 : D'Art Clinical Expert Report (CE Mark
ETH.MESH.02280771-	requirement) Email - An email discussing the Clinical Expert
ETH.MESH.02280772	Report
ETH-37788-	Plaintiffs'-3002: Gynecare Clinical Expert Report - Clinical Expert
ETH-37793	Report on Prolift
	Plaintiffs'-3003: Gynecological Journal - A journal article that
ETH-02800-	discusses the conceptual advances in the surgical management
ETH-02812	of genital prolapse
ETH.MESH.02341522-	- O - 200   p : 0 - 200   p
ETH.MESH.02341527	Plaintiffs'3004: Gynecare Prolift - Instructions for use
	D1 - Amended Cross Notice of Depo of Charlotte Owens
	Charlotte Owens Deposition - 09-13-12
	Ondrotte Offens Deposition - 03-10-12

ETH.MESH.02270857-	Plaintiffs'-3005: D'Art- Conversation with Prof Jacquetin Email -
ETH.MESH.02270858	An email discussing the use of vypro by a specific surgeon
	,, , ,
	Plaintiffs'-3006: VOC & Follow Up for Clinical Information
ETH.MESH.00127026-	needed by late January for PROLJFT* (confidential) Email - An
ETH.MESH.00127030	email that discusses the results of Marketing research
ETH.MESH.04243020-	3
ETH.MESH.04243022	Plaintiffs'-3007: TVM Email - An email discussing violations
	Plaintiffs'-3008 - Article entitled Safety of Transvaginal Mesh
	procedure: Retrospective study of 684 patients
	Plaintiffs'-3009: GYNECARE PROUFT* PELVIC FLOOR
ETH.MESH.02273358-	REPAIR SYSTEM (PROJECT D'ART) Email - An email that
ETH.MESH.02273359	discusses the Device Design Safety Assessment.
	Plaintiffs'-3010: Classification of meshes based on porosity and
	filament type as follows - A memo that discusses the
ETH.MESH.00869983	classifications and complications of mesh
	Thomas A. Barbolt, Ph.D. Depo Cuts
	October 9, 2012
	October 10, 2012
	August 14, 2013
	August 15, 2013
	January 7, 2014
	January 8, 2014
ETH.MESH.03919143 -	Gynemesh holding force in tissue Email - An email discussing
ETH.MESH.03919144	issues with mesh
ETH.MESH.02276129 -	TVM Procedure Email - An email discussing various ideas and
ETH.MESH.02276130	possible issues
ETH.MESH.02270770 -	Distal Strap Location For Anterior Implant Email - An email that
ETH.MESH.02270772	discusses procedure questions
ETH.MESH.00900574 -	Observation of tissue tearing Email - An email that discusses
ETH.MESH.00900575	tissue tearing
ETH.MESH.01986683 -	TVM and TVT 2/12 Email - An email that discusses tissue
ETH.MESH.01986683	tearing
ETH.MESH.00900352 -	
ETH.MESH.00900353	
AND	
ETH.MESH.00912899 -	1
ETH.MESH.00912903	Mesh Straps - a thought Email - An email that discusses straps
ETH.MESH.00914705 -	
ETH.MESH.00914705	Mesh strap transition Email - An email discussing mesh straps
ETH.MESH.03921403 -	
ETH.MESH.03921403	Prolift System - A memo discussing features to improve Prolift

	·
ETH.MESH.00133497 -	Email - An email that discusses the attached summary of
ETH.MESH.00133499	meeting at AAGL
ETH.MESH.03921408 -	Visit November 10, 2005 Email - An email discussing the issues
ETH.MESH.03921408	a surgeon is facing with the use of Prolift
ETH.MESH.03911684 -	PROLIFT Improvements - Pr Eberhard (Frauenfeld, Switzerland)
ETH.MESH.03911687	Email - An email discussing improvements to Prolift
ETH.MESH.00849867 -	
ETH.MESH.00849869	Prolift help Email - An email discussing issues with Prolift
ETH.MESH.00850307 -	
ETH.MESH.00850310	Hello from Tokyo Email - An email discussing mesh arms
ETH.MESH.00803777 -	Minutes: Prolift Users Forum - A memo that includes the minutes
ETH.MESH.00803782	from the Prolift forum
ETH.MESH.00847233 -	
ETH.MESH.00847235	PROLIFT email - An email discussing a technique used
ETH.MESH.00847401 -	
ETH.MESH.00847401	Complaint Email - An email discussing a complaint with Prolifi
ETH.MESH.00870465 -	Minutes Hamburg Meeting Email - An email containing the
ETH.MESH.00870476	minutes from a meeting in Hamburg
ETH.MESH.05454207 -	Photos cadaver lab Email - An email containing photos from a
ETH.MESH.05454208	cadaver lab
	Lightning Project Charter PowerPoint Presentation - A
ETH.MESH.00267733 -	PowerPoint that discusses the request for charter, proposed
ETH.MESH.00267872	product, value proposition, and market/financial
ETH.MESH.03912616 -	PROLIFT Mesh Design Email - An email that discusses the
ETH.MESH.03912618	mesh design of Prolift
ETH.MESH.06616651 -	, and the second
ETH.MESH.06616651	Case Email - An email discussing complaints/issues of a case
ETH.MESH.13263449 -	<b>3 5</b>
ETH.MESH.13263449	Case Email - An email discussing complaints/issues of a case
ETH.MESH.00902149 -	PROLIFT+M Design Risk Documentation Email - An email
ETH.MESH.00902151	discussing potential risks associated with Prolift +M
ETH.MESH.03650906 -	PROLIFT+M Design Risk Documentation Email - An email
ETH.MESH.03650909	discussing potential risks associated with Prolift +M
	Pelvic Organ Prolapse Repair: Lesson Learned from the
ETH.MESH.01218423 -	PROLIFT Experience - A memo that discusses what surgeons
ETH.MESH.01218424	like and what the issues are
ETH.MESH.00906661 -	FDA response: PROLIFT Email - An email discussing the FDA
ETH.MESH.00906661	response to Prolift
ETH.MESH.00012267 -	Design Requirements Matrix - A memo that discusses the
ETH.MESH.00012303	design requirements of Prolift +M
ETH.MESH.00836975 -	Mesh Shrinkage Email - An email that discusses mesh
ETH.MESH.00836977	shrinkage in Prolift

ETH.MESH.09650853 -	Invention Disclosure Form - A form that discusses the invention
ETH.MESH.09650863	disclosures of Areal implant with body embedded properties.
ETH.MESH.12003000 -	and one of the dark men and y embedded properties.
ETH.MESH.12003012	Prolift - A memo discussing Prolift in detail
ETH.MESH.00857704 -	T-PRO_TPP.ppt Email - An email discussing the advantages
ETH.MESH.00857705	over +M
ETH.MESH.01239420 -	RAB - T-Pro redefinition Email - An email discussing
ETH.MESH.01239424	impressions from RAB
ETH.MESH.07171404 -	Promisa Take Away Messages Email - An email discussing the
ETH.MESH.07171406	highlights from a meeting
HMESH ETH 02094649 -	Trip Summary: Dr. Neuman Email - An Email discussing the
HMESH_ETH_02094650	summary of a trip
ETH.MESH.01254550 -	Interesting data on Dyspareunia and PROLIFT+M Email - An
ETH.MESH.01254554	email discussing an upcoming meeting
	Methodology to Prevent Mesh Torsion during Vaginal Mesh
ETH.MESH.02011262 -	Placement Email - An email containing notes about sheath
ETH.MESH.02011267	invention
ETH.MESH.09122371 -	
ETH.MESH.09122372	
AND	
ETH.MESH.07515083 -	NEO sample requirements for pilot sheep study Email - An email
ETH.MESH.07515104	discussing the sheep pilot study
ETH.MESH.07237575 -	Actually a few more Questions Email - An email discussing
ETH.MESH.07237576	questions about mesh arms
ETH.MESH.16196954 -	
ETH.MESH.16196977	Report - A memo discussing the meeting regarding Prolift Mesh
	Cornu, J.N., Sebe, P., Peyrat, L., et al. "Midterm Prospective
	Evaluation of TVT-Secur Reveals High Failure Rate," European
	Urology 58 (2010) 157-161.
	Saltz, S., Miklos, J., Moore, R., et al., "Multicenter Short Term
	Assessment of Patients Undergoing the New Tension Free
	Vaginal Tape Secur Procedure for Treatment of Stress Urinary
	Incontinence" (Abstract)
	Danford, J., Osborn, D., Reynolds, W., Biller, D., Dmochowski,
	R., "Postoperative Pain Outcomes After Transvaginal Mesh
	Revision", Int. Urogynecol J., 2014
	The American College of Obstetricians and Gynecologists
	Practice Bulletin, "Urinary Incontinence in Women", Vol. 126,
	No. 5, November 2015, 66-81

	The American College of Obstetricians and Gynecologists Practice Bulletin Summary, "Urinary Incontinence in Women", Vol. 126, No. 5, November 2015, 1120-1122
	Mary, C., Marois, Y., King, M., et al. "Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery," ASAIO Journal, 1998, pp. 199-206.
	Blandon, R., Gebhart, J., Trabaco, E., Ktingele, C. "Complications from Vaginally Placed Mesh in Pelvic Reconstructive Surgery," Int. Urogynecol J (2009) 20:523-531.
	D.F. Burkley - Sept. 30, 1987 - IR Microscopy of explanted Prolene received from Prof. R. Guidoin (14 pp.)
	Jongebloed, W.L., Figueras, M.J., Humalda, D., Blanksma, L.J. and Worst, J.G.F. "Mechanical and Biochemical Effects of Man-Made Fibers and Metals in the Human Eye, a SEM-study," Documents Ophthalmologics 61, 303-312 (1986).
	Treatment of Stress Urinary Incontinence with Gynecare TVT Secur System (38 pp.)
ETH.MESH.00870465 - ETH.MESH.00870476	Minutes Hamburg Meeting Email - An email containing minutes from the Hamburg meeting
ETH.MESH.03460813 - ETH.MESH.03460853	Gynecare Prolift Surgeon's Resource Monograph - A memo discussing Prolift in detail
ETH.MESH.03722384 - ETH.MESH.03722386	Mesh + Anti-Proliferative agent Email - An email discussing issues that are happening
ETH.MESH.07201006	Exhibit 3 - Gynecare Prolift systems
ETH.MESH.09888187 - ETH.MESH.09888223	Seven Year Data for Ten Year Prolene Study - A memo discussing the seven year data for the ten year Prolene study
ETH.MESH.12831405 - ETH.MESH.12831406	Crack Depth - A memo discussing the crack depth in Prolene sutures
ETH.MESH.15955438- ETH.MESH.15955439	Prolene Microcracks - A memo discussing microcracks in Prolene
ETH.MESH.15955440 -	Human Retrieval Specimens - A memo discussing prolene
ETH.MESH.15955442	sutures and their issues from human specimens  Examination of Sutures from Human Retrieval - A memo
ETH.MESH.15955462 - ETH.MESH.15955468	discussing the examination of sutures retrieved from human specimens
	David B. Robinson, MD - 03-13-12

	Plaintiffs-494 - Curriculum Vitae of David B. Robinson, MD
	Plaintiffs-495 - PowerPoint, "Graft or No Graft, A. Arnaud M.D.,
	Scientific Director Europe Gynecare
ETH.MESH.00034725 and	
ETH.MESH.00034730	Plaintiffs-496 - Email dated April 21, 2009 and attachment
	Plaintiffs-497 - A Systematic Review of the Gynecare Prolift
ETH.MESH.00596225-	Pelvic Floor Repair System in Pelvic Floor Repair System in
ETH.MESH.00596264	Pelvic Organ Prolapse
ETH.MESH.00577756 and	
ETH.MESH.00577757	Plaintiffs-498 - Email chain, top one dated Feb. 19, 2010
ETH.MESH.00578261-	
ETH.MESH.00578263	Plaintiffs-499 - Email chain, top one dated June 7, 2010
ETH.MESH.00578325-	, , , , , , , , , , , , , , , , , , , ,
ETH.MESH.00578328	Plaintiffs-500 - Email chain, top one dated June 13, 2010
ETH.MESH.01798410 and	, , , , , , , , , , , , , , , , , , , ,
ETH.MESH.01798411	Plaintiffs-501 - Email chain, top one dated Sept. 9, 2010
	David B. Robinson, MD - 03-14-12
ETH.MESH.00832920 AND	
ETH.MESH.00832921	Plaintiff's-502 - Email chain, top one dated 12 July 2006
	Plaintiff's-503 - Medical Device Risk Management/Company
ETH.MESH.00839729-	Procedure for Medical Device Risk Management Plan: PR602-
ETH.MESH.00839732	003
ETH.MESH.01782850 -	
ETH.MESH.01782852	Plaintiff's-504 - Email chain, top one dated 20 June 2006
ETH.MESH.00326842 -	, 1
ETH.MESH.00326846	Plaintiff's-505 - Email chain, top one dated 05 Nov. 2007
	, <b>,</b>
	Plaintiff's-506 - Article entitled "Midterm Prospective Evaluation
	of TVT-Secur Reveals High Failure Rate" (5 pp.)
ETH.MESH.00841668 AND	
ETH.MESH.00841669	Plaintiff's-507 - Email chain, top one dated 24 Nov. 2006
	Plaintiff's-508 - Brochure, "Pelvic Organ Prolapse, Get the
	Facts, Be Informed, Make Your Best Decision (9 pp.)
ETH.MESH.00847816	Plaintiff's-509 - Email chain, top one dated 10 Jan. 2007
	Plaintiff's-510 - PowerPoint Slides (2 pp.)
ETH.MESH.00841557 AND	\ FF /
ETH.MESH.00841558	Plaintiff's-511 - Email chain, top one dated 08 Oct. 2007
ETH.MESH.00271215 AND	, , , , , , , , , , , , , , , , , , , ,
ETH.MESH.00271216	Plaintiff's-512 - Email dated 29 Oct. 2008
ETH-17416 - ETH-17419	Plaintiff's-513 - Email dated September 04, 2008
ETH.MESH.00872521	Plaintiff's-514 - Email dated 22 Dec. 2008
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Plai     ETH.MESH.00311390 AND     ETH.MESH.00310865 -     ETH.MESH.00310882     Plai     ETH.MESH.00310882     Plai     Usir     Pelv     Plai     Usir     Pelv     Plai     ETH.MESH.00142517 -     ETH.MESH.00142568     ETH.MESH.00012090 -     ETH.MESH.00012090 -     ETH.MESH.00012099 -     ETH.MESH.00012009 -     ETH.MESH.00012009 -     ETH.MESH.00012009 -     ETH.MESH.00012089     ETH.MESH.00012089     Plai     Rep     ETH.MESH.00829380 -     Plai     Plai     Rep     ETH.MESH.00829380 -     Plai     Plai	intiff's-515 - Email dated 19 Feb. 2009 intiff's-516 - Skipped Exhibit No No Document intiff's-517 - Memorandum-Draft, Re: 08/13/2010 Meeting utes - Gynecare Prolift intiff's-518 - Risk Management Report (Legacy) Gynecare
Plain	intiff's-516 - Skipped Exhibit No No Document intiff's-517 - Memorandum-Draft, Re: 08/13/2010 Meeting utes - Gynecare Prolift
ETH.MESH.00311390 AND ETH.MESH.00311391 Minu ETH.MESH.00310865 - Plai ETH.MESH.00310882 Prol  Plai Usir Pelv  Plai ETH.MESH.00142517 - Usir ETH.MESH.00142568 Pelv ETH.MESH.00012090 - Plai ETH.MESH.00012163 tech ETH.MESH.00012009 - Plai ETH.MESH.00012089 Tec Plai Plai Rep ETH.MESH.00829380 - Plai	intiff's-517 - Memorandum-Draft, Re: 08/13/2010 Meeting utes - Gynecare Prolift
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Plai ETH.MESH.00142517 - Usir ETH.MESH.00142568 Pelv ETH.MESH.00012090 - Plai ETH.MESH.00012163 tech ETH.MESH.00012009 - Plai ETH.MESH.00012089 Tech Plai Plai Rep ETH.MESH.00829380 - Plai	ng Mesh, David B. Robinson, MD, Center for Continence and
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ETH.MESH.00142517 - Usir ETH.MESH.00142568 Pelv ETH.MESH.00012090 - Plai ETH.MESH.00012163 tech ETH.MESH.00012009 - Plai ETH.MESH.00012089 Tech Plai Plai Rep ETH.MESH.00829380 - Plai	
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ETH.MESH.00012163 tech ETH.MESH.00012009 - Plai ETH.MESH.00012089 Tec Plai Plai Rep ETH.MESH.00829380 - Plai	intiff's-521 - Clinical Study Report, Evaluation f the TVM
ETH.MESH.00012009 - Plai ETH.MESH.00012089 Tec Plai Plai Plai Rep ETH.MESH.00829380 - Plai	nnique for treatment of genital prolapse
ETH.MESH.00012089 Tec	intiff's-522 - Clinical Study Report, Evaluation of the TVM
Plai Plai Rep ETH.MESH.00829380 - Plai	chnique for treatment of genital prolapse
Plai   Rep   ETH.MESH.00829380 -   Plai	intiff's-523 - PowerPoint, "The TVM Data" (9 pp.)
Rep ETH.MESH.00829380 - Plai	intiff's-524 - PowerPoint, "Gynecare Prolift* Pelvic Floor
ETH.MESH.00829380 - Plai	· •
	pair Systems" (19 pp.)
ETH.MESH.00829443 PTO	intiff's-525 - Project: Literature Review - Pelvic Organ
Dia	lapse Repair Procedures
	intiff's-526 - Clinical Expert Report, Gynecare Prolift* Pelvic
	or Repair System
	intiff's-527 - Clinical Expert Report, Gynecare Prolift* Pelvic
	or Repair System
Plai	intiff's-528 - DVD of Surgical Video Clips
	intiff's-528A - Anatomical Animation Screen Shot Number 1
·	vid B. Robinson, MD - 07-24-13
ETH.MESH.00679574 -	
	22 - Spreadsheet, "Incontinence Preceptors"
	23 - 12/303 email string from Zenobia Walji to Scott
ETH.MESH.02270951 Ciar	rrocca
ETH.MESH.00642325 -	
ETH.MESH.00642331 T-92	24 - 10/29/07 email string from Kevin Mahar to Ted Foltyn
ETH.MESH.01795834 - T-92	25 - Document, "Clinical Evaluation Report Gynecare TVT,"
ETH.MESH.01795873 etc,	August 2, 2010
	26 - PowerPoint, "Incontinence Platform WW Marketing
ETH.MESH.02248848 T-92	nm Update, August 19th"
ETH.MESH.02270951 Ciar ETH.MESH.00642325 - ETH.MESH.00642331 T-92 ETH.MESH.01795834 - T-92 ETH.MESH.01795873 etc, T-92 ETH.MESH.02105223 Tea	rrocca  24 - 10/29/07 email string from Kevin Mahar to Ted Foltyn  25 - Document, "Clinical Evaluation Report Gynecare TVT,"  August 2, 2010

ETH.MESH.01782850 -	T-928 - 6/20/06 e-mail chain from David Robinson to Harel
ETH.MESH.01782852	Gadot, et al.
	T-929 - 2/27/09 email from Jason Hernandez to Nicholas
ETH.MESH.00134794 -	Antoun, et al., with attached PowerPoint, "TVT World Registry,
ETH.MESH.00134795	EWHU Board March 2, 2009"
ETH.MESH.03171093 -	T-930 - 6/9/06 email string from Anna Gray to David Robinson,
ETH.MESH.03171094	et al.
	T-931 - Confidential Interim Statistical Report, an Evaluation of
ETH.MESH.04499687 -	the Gynecare TVT Secur System for the Treatment of Stress
ETH.MESH.04499742	Urinary Incontinence
ETH.MESH.00153967 -	T-932 - 11/14/06 email string from David Robinson to Dharini
ETH.MESH.00153968	Amin and Kevin Mahar
ETH.MESH.00839918 -	T-933 - 9/20/06 email from David Robinson with attachment,
ETH.MESH.00839919	PowerPoint, TVTs All Complaints up to 20 September 2006"
ETH.MESH.03922618 -	T-934 - 3/14/07 email from David Robinson to Axel Arnaud, et
ETH.MESH.03922619	al., with attachment re 5 week results
ETH.MESH.06479808 -	T-935 - Clinical Study Report, Evaluation of the TVT Secur
ETH.MESH.06479885	System for Stress Urinary Incontinence, Final Draft June 2012
	T-936 - Document titled "An Evaluation of the Gynecare TVT
	SECUR System (Tension-Free Support for Incontinence) for the
ETH.MESH.00147163	Treatment of Stress Urinary Incontinence"
ETH.MESH.03913651 -	T-937 - 6/1/07 meeting minutes CDMA Europe Meeting, Urinary
ETH.MESH.03913615	Incontinence Platform
ETH.MESH.02916532 -	T-938 - July 2009 draft Clinical Study Evaluation of the TVT
ETH.MESH.02916615	Secur System for Stress Urinary Incontinence
ETH.MESH.01784428 -	T-939 - 12/20/06 e-mail string from David Robinson to Allison
ETH.MESH.01784435	London Brown, et al.
ETH.MESH.02340568 -	
ETH.MESH.02340590	T-940 - TVT Secur package insert
ETH.MESH.00311811 -	T-941 - 3/7/07 email string from David Robinson to Dan Smith
ETH.MESH.00311813	and Axel Arnaud
ETH.MESH.00163952 -	
ETH.MESH.00163960	T-942 - Gynecare TVT Secur* System: Key Technical Points
ETH.MESH.00523617 -	T-943 - Document titled "Summary of Gynecare TVT Secur*
ETH.MESH.00523618	System Critical Steps"
	T-944 - 2/5/07 email from Dharini Amin to Scott Serels, et al.,
ETH.MESH.00729815 -	with attached document, "TVT Breakout Session-Moderator
ETH.MESH.00729821	Script"
ETH.MESH.00153882 -	T-945 - 12/17/06 email chain from David Robinson to Andrew
ETH.MESH.00153885	Meek, et al.

ETH.MESH.00327060 -	
ETH.MESH.00327060 -	T-946 - 11/12/07 email string from David Robinson to Mark Yale,
ETH.MESH. 00327063	et al.
ETH.MESH.02634983 -	
ETH.MESH.02634993	T-947 - Issue Report TVT S 2008
ETH.MESH.05208708 -	T-948 - Email string with redacted first page; 1/8/08 from Aran
ETH.MESH.05208710	Maree to Christina Bielinski
	T-949 - Journal of Urology article by Piet Hinoul, et al. "A
	Randomized, Controlled Trial Comparing an Innovative Single
ETH.MESH.00576529 -	Incision Sling with an Established Transobturator Sling to Treat
ETH.MESH.00576540	Female Stress Urinary Incontinence"
	T-950 - Article by Lekha S. Hota, MD, et al. "TVT-Secur
ETH.MESH.04474756 -	(Hammock) Versus TVT-Obturator: A Randomized Trial of
ETH.MESH.04474760	Suburethral Sling Operative Procedures"
ETH.MESH.02634889 -	<u> </u>
ETH.MESH.02634899	T-951 - Issue Report TVT S 2008
ETH.MESH.02635648-	•
ETH.MESH.02635658	T-952 - Issue Report TVT S 2008
	T-953 - Document withdrawn
ETH.MESH.06927248 -	T-954 - 3/19/10 email string from Dan Smith to Paul DeCosta, et
ETH.MESH.06927249	al.
	T-955 - PowerPoint, Ethicon Women's Health and Urology,
ETH.MESH.03643186	Brand Equity Study, Final Report, January, 2010
	David B. Robinson, MD - 07-25-13
ETH.MESH.00756100 -	,
ETH.MESH.00756102	T-956 - Document titled "Arrowhead Campaign, May 2003'
ETH.MESH.00128358 -	T-957 - 5/11/04 email string from Ettore Carino to Kimberly
ETH.MESH.00128360	Mullarkey, et al.
ETH.MESH.00440005 -	T-958 - 1/5/05 email string from Laura Angelini to Ronnie
ETH.MESH.00440007	Toddywala, et al.
	T-959 - 5/6/05 email from Allison London Brown to Nancy
ETH.MESH.0526473	Leclair, et al.
ETH.MESH.01809080 -	T-960 - 12/14/04 memo to Paul Parisi and Dan Smith from
ETH.MESH.01809081	Becky Leibowitz
ETH.MESH.04048515 -	
ETH.MESH.04048520	T-961 - 6/18/08 KOL Interview; Carl G. Nilsson
ETH.MESH.01822361 -	·
ETH.MESH.01822363	T-962 - 10/18/06 email from Dan Smith to Harel Gadot, et al.
	T-963 - 8/16/05 email from Allison London Brown to Kevin
ETH.MESH.00525573	Mahar, et al.
ETH.MESH.04985249 -	
ETH.MESH.04985252	T-964 - 8/23/05 email string from Paula Evans to Sungyoon Rha

ETILMENI 00050450	TOCK Marketing piece titled "The Compagns TV/T Femily of
ETH.MESH.00658453 -	T-965 - Marketing piece titled "The Gynecare TVT Family of
ETH.MESH.00658458	Products, 3 Sui Solutions, Delivering Data, Safety & Choice
ETH.MESH.04081468 -	T-966 - Document, "Gynecare TVT-Secur - Overview of 2008
ETH.MESH.04081473	Product Complaints Reported as MDR Serious Injuries"
	T-967 - PowerPoint, "The Science of 'What's Left
	Behind'Evidence & Follow-Up of Mesh Use for SUI, Nick
ETH.MESH.00271641	Franco, MD, Naples, FL"
ETH.MESH.01784823 -	T-968 - Clinical Expert Report, laser-cut mesh for Gynecare
ETH.MESH.01784828	TVT, etc., March 7, 2006
ETH.MESH.00687819 -	T-969 - 12/19/05 email string from Kevin Mahar to Price St.
ETH.MESH.00687822	Hilaire, et al
ETH.MESH.00007091 -	T-970 - 2/6/09 email with attachment from Jennifer Haby to
ETH.MESH.00007092	Melissa Chaves, et al.
ETH.MESH.01782154 -	T-971 - 1/20/06 email string from David Robinson to Carolyn
ETH.MESH.01782156	Brennan and Dharini Amin
ETH.MESH.00067902 -	
ETH.MESH.00067904	T-972 - 1/27/05 email string from Carolyn Brennan to Paul Parisi
	T-973 - 3/25/05 email string from Charlotte Owens to Scott
ETH.MESH.02271018	Ciarrocca
ETH.MESH.01811770 -	
ETH.MESH.01811772	T-974 - 12/10/04 email string from Steve Bell to Dan Smith, et al.
	T-975 - 2/6/06 email string from David Robinson to Carolyn
ETH.MESH.00847536	Brennan and Dharini Amin
ETH.MESH.03531443 -	T-976 - 5/7/08 email string from Carolyn Brennan to Barbara
ETH.MESH.03531448	Smackover, et al.
ETH.MESH.00845911 -	T-977 - 12/21/05 email from David Robinson to Martin Weisberg
ETH.MESH.00845912	and Michael Connaughton
ETH.MESH.02122903 -	T-978 - 5/26/09 email string from Carolyn Brennan to Jason
ETH.MESH.02122905	Hernandez with attachment
E111.WEG11.02122303	Fichianacz with attachment
	T- 979 - Document, "Risk?benefit Analysis, Re: Page 4, line 3 of
ETH.MESH.00823660	Clinical Expert Report; Gynecare TVT Secur System"
ETH.MESH.02652985 -	Cililical Expert Neport, Gyriecale TVT Secur System
	T 090 Jaqua Banart TVT O 2005
ETH.MESH.02652987	T-980 - Issue Report TVT O 2005
ETH.MESH.02627466 -	T 004 Janua Danart TV/T Datmaraukia 0005 0007
ETH.MESH.02627471	T-981 - Issue Report TVT Retropubic 2005-2007
ETH.MESH.02627418 -	T 000 - Issa - Decent TV/T Dates - It's 0005 0007
ETH.MESH.02627421	T-982 - Issue Report TVT Retropubic 2005-2007
ETH.MESH.00832937 -	T-983 - 2/26/07 email string from David Robinson to Joseph
ETH.MESH.00832939	Megan

ETH MECH 00142122	
ETH.MESH.00143133 -	TOOA Decree at titled !!Ohio stiene 8   Londline Ctatements!
ETH.MESH.00143135	T-984 - Document titled "Objections & Handling Statements"
ETIL MEQUA 00750004	T 005 40/00/05 and ill frame David Dahima and to Cicalla Danat
ETH.MESH.00756984	T-985 - 10/28/05 email from David Robinson to Giselle Bonet
ETH.MESH.08003263 -	T-986 - Patient brochure, "The Choice to End Stress Urinary
ETH.MESH.08003278	Incontinence"
ETH.MESH.01222075 -	T-987 - 3/6/06 memo to Marty Weisberg and David Robinson
ETH.MESH.01222079	from Gene Kammerer
ETH.MESH.06696367 -	T-988 - Memo to Raimo Sump and Allison London-Brown from
ETH.MESH.06696379	Katherine Seppa
	T-989 - Article by Tincello, et al. "The TVT Worldwide
	Observational Registry for Long-Term Data: Safety and Efficacy
	of Suburethral Sling Insertion Approaches for Stress Urinary
	Incontinence in Women"
	David B. Robinson, MD - 08-23-12
ETH.MESH.02766207	P-805 - Minutes of telephone conference 07 Jan 06
ETH.MESH.02316936 -	
ETH.MESH.02316938	P-806 - Email string, 1/9/06
ETH.MESH.02766191 -	
ETH.MESH.02766192	P-807 - Minutes of telephone conference 12 Jan. 06
ETH.MESH.00850664 -	
ETH.MESH.00850667	P-808 - Email string, 1/24/06 - 1/26/06
ETH.MESH.00846990 -	
ETH.MESH.00846991	P-809 - Email string, 4/25/06
ETH.MESH.00520725 -	
ETH.MESH.00520728	P-810 - Email string 6/23/06 - 6/27/06
ETH.MESH.00844878	P-811 - Email, 10/17/07, to Gauld and others from Robinson
ETH.MESH.00844879 -	
ETH.MESH.00844880	P-812 - Documents
ETH.MESH.02331443-	
ETH.MESH.02331459	P-813 - Case report form, Subject ID 10026
ETH.MESH.02331030 -	
ETH.MESH.02331053	P-814 - Case report form, Subject ID 10010
ETH.MESH.02330854 -	
ETH.MESH.02330874	P-816 - Case report form, Subject ID 10003
	P-817 - Presentation entitled "Characteristics of Synthetic
	Materials Used in Prolapse and Incontinence Surgery"
	P-818 - Presentation entitled "Lightning", 9/6/06
ETH.MESH.01760852	P-819 - Email, 9/23/06 to Meier from Robinson
ETH.MESH.01760863	P-820 - Ultrapro Clinical Expert Bibliography
ETH-00295 - ETH-00300	P-821 - Gynecare Prolift Instructions for Use
ETH.MESH.0234152	P-822 - Gynecare Prolift Instructions for Use
ETH-00295 - ETH-00300	P-821 - Gynecare Prolift Instructions for Use

	P-823 - Ethicon Pelvic Organ Prolapse brochure
	P-824 - Ethicon Pelvic Organ Prolapse brochure
	P-825 - Curriculum vitae
	David B. Robinson, MD - 09-11-13
	T-1250 - 1/3/06 email from Mark Yale to Gary Borkes, et al. with
ETH.MESH.06860410	attachment
ETH.MESH.05498580 -	T-1251 - 12/2/05 email string from Quentin Manley to Barbara
ETH.MESH.05498583	Schwartz
ETH.MESH.06893564 -	T-1252 - 9/25/06 email string from Harel Gadot to David
ETH.MESH.06893565	Robinson and Dan Smith
	T-1253 - 11/3/06 email from Carolyn Brennan to Mark Yale, et
ETH.MESH.00324109	al.
ETH.MESH.00329259 -	T-1254 - 1/19/07 email string from Mark Yale to Carol Holloway,
ETH.MESH.00329260	et al.
ETH.MESH.03845446 -	T-1255 - 10/30/07 email strong from Darryl Harkness to Aran
ETH.MESH.03845450	Maree
	T-1256 - Document entitled "Gynecare TVT Secur System -
ETH.MESH.00823421 -	Australian Postmarket Surveillance Review Meeting October 31,
ETH.MESH.00823422	2007"
ETH.MESH.00533093 -	T-1257 - Document entitled "IIS Study Monthly Update: May
ETH.MESH.00533094	2010"
	T-1258 - Article by Barbert, et al. titled "Single-Incision Mini-Sling
ETH.MESH.06358092 -	Compared with Tension-Free Vaginal Tape for the Treatment of
ETH.MESH.06358101	Stress Urinary Incontinence"
	T-1259 - Article by Cornu, et al. titled "Midterm Prospective
	Evaluation of TVT-Secur Reveals High Failure Rate"
	T-1260 - 6/21/08 email string from Scott Ciarrocca to David
ETH.MESH.006861281	Robinson and Dan Smith
ETH.MESH.00529928	T-1261 - List of investigator initiated studies
	T-1262 - Handwritten sheet prepared by Tom Cartmell, Esq.
	headed "TVT: The Benefit"
	T-1263 - Handwritten sheet prepared by Tom Cartmell, Esq.
	headed "Would 1% Deaths Related to TVT Be Too Much Risk?"
	T-1264 - Handwritten sheet prepared by Tom Cartmell, Esq.
	headed "Would 1% of Permanent Pelvic Pain be Too Much
	Risk?"
	T-1265 - Document entitled "Ethicon, Inc. Worldwide Complaint-
ETH.MESH.0128704	Reporting Statement"
ETH.MESH.00692884 -	T-1266 - 1/16/06 email string from Dharini Amin to David
ETH.MESH.00692885	Robinson, et al.

	T 1267 Article by Word et al. titled "A prespective multicenter
	T-1267 - Article by Ward, et al. titled "A prospective multicenter
ETIL MECIL 00400424	randomized trial of tension0free vaginal tape and
ETH.MESH.00160131 -	colposuspension for primary urodynamic stress incontinence:
ETH.MESH.00160138	Two-year follow-up"
ETI   MEQUI 00050007	T 4000 A Cala la Alliana a afral III ana Tana Dan Italia (a
ETH.MESH.00658807	T-1268 - Article by Nilsson, et al. "Long Term-Results" etc.
ETH.MESH.03930120 -	T 4000 A Cala la Alliana a afral 110 a an Mara Falla a all afra
ETH.MESH.03930123	T-1269 - Article by Nilsson, et al. "Seven-Year Follow-up" etc.
ETH.MESH.00355003 -	T 4070 A (;     A   A   );
ETH.MESH.00355007	T-1270 - Article by Nilsson, et al. "Eleven years prospective" etc.
ETH.MESH.08299913 -	T-1271 - Article by Nilsson, et al. "Seventeen Years' follow-up"
ETH.MESH.08299917	etc.
ETH.MESH.00339437 -	
ETH.MESH.00339442	T-1272 - Gynecare TVT brochure
ETH.MESH.00658058 -	
ETH.MESH.00658065	T-1273 - Gynecare TVT brochure
ETH.MESH.01186068 -	
ETH.MESH.01186072	T-1274 - Gynecare TVT brochure
ETH.MESH.8003215 -	
ETH.MESH.08003230	T-1275 - Gynecare TVT brochure
ETH.MESH.03259439 -	
ETH.MESH.03259440	T-1276 - 4/24/089 email string from Judi Gauld to Colin Urquhart
ETH.MESH.04523637 -	T-1277 - Article by Tincello, et al. "The TVT Worldwide
ETH.MESH.04523642	Observational Registry" etc.
ETH.MESH.02340504 -	
ETH.MESH.02340567	T-1278 - Gynecare TVT Instructions for Use
	T-1279 - Enlarged excerpt of Gynecare TVT IFU
ETH.MESH.00440005 -	T-1280 - 1/5/05 email string from Laura Angelini to Ronnie
ETH.MESH.00440007	Roddywala, et al.
	T-1281 - 8/28/06 email from Gene Kammerer to Jacqueline
ETH.MESH.08334244	Flatow
ETH.MESH.00584527	T-1282 - PowerPoint, "Second half photo presentation"
ETH.MESH.00294195 -	T-1283 - Article by Moalli, et al. "Tensile properties of five
ETH.MESH.00294203	commonly used mid-urethral slings relative to the TVT"
ETH.MESH.01218019	T-1284 - Documents, "Design FMEA TVT LCM Project"
ETH.MESH.03910418 -	T-1285 - 11/26/02 email from Axel Arnaud to Dr. Reinhardt
ETH.MESH.03910421	Juraschek, et al.
ETH.MESH.02319408 with	
attachment	
ETH.MESH.02319409	T-1286 - 4/17/07 email from David Robinson to Cyrus Guidry
ETH.MESH.06852118 -	T-1287 - 5/26/00 memo to P. Cecchini from Richard W.
ETH.MESH.06852129	Hutchinson with enclosure
I	

	T-1288 - PowerPoint, "Characteristics of Synthetic Materials
ETH.MESH.00838428	Used in Prolapse and Incontinence Surgery"
	T-1289 - PowerPoint, "EWH&U Clinical Development Update
ETH.MESH.00824100	July 2010
	T-1290 - Article by Walters and Weber, "Which sling for which
	SUI patient?"
	T-1291 - Article by Kjolhede, "Long-term efficacy of Burch
	colposuspension: A 14-year follow-up study"
	T-1292 - Article by Olsson, et al. "Long-term efficacy of the
	tension-free vaginal tape procedure for the treatment of urinary incontinence"
	Incontinence
	T-1293 - Article by Serati, et al. "Tension-free Vaginal Tape for
	the Treatment of Urodynamic Stress Incontinence: Efficacy and
	Adverse Effects at 10-Year Follow-Up"
ETH.MESH.09748865 -	Adverse Enects at 10-1 car I onow-op
ETH.MESH.09748868	T-1294 - Consultancy Agreement
ETH.MESH.05136675 -	T-1295 - 11/12/10 email string from Aaron Kirkemo to Lennox
ETH.MESH.05136678	Hoyte, et al.
	Previously Marked Exhibits:
	T-926 - PowerPoint, "Incontinence Platform WW Marketing
ETH.MESH.02105223	Team Update, August 19th"
ETH.MESH.00153967 -	T-932 - 11/14/06 email string from David Robinson to Dharini
ETH.MESH.00153968	Amin and Kevin Mahar
ETH.MESH.06479808 -	T-935 - Clinical Study Report, Evaluation of the TVT Secur
ETH.MESH.06479885	System for Stress Urinary Incontinence, Final Draft June 2012
	T-949 - Journal of Urology article by Piet Hinoul, et al. "A
	Randomized, Controlled Trial Comparing an Innovative Single
ETH.MESH.00576529 -	Incision Sling with an Established Transobturator Sling to Treat
ETH.MESH.00576540	Female Stress Urinary Incontinence"
ETIL MEGIL 0 / / T / T C	T-950 - Article by Lekha S. Hota, MD, et al. "TVT-Secur
ETH.MESH.04474756 -	(Hammock) Versus TVT-Obturator: A Randomized Trial of
ETH.MESH.04474760	Suburethral Sling Operative Procedures"
ETIL MECIL 00074040	T-973 - 3/25/05 email string from Charlotte Owens to Scott
ETH.MESH.02271018	Ciarrocca
	T-2111 T-3137
	Sean M. O'Bryan - 05-18-12
	750 - CV of Sean M. O'Bryan
ETH.MESH.00875541-	750 - GV OI Seall IVI. O DI Yali
ETH.MESH.00875543	751 - 7/22/02 Preservation Notice
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753 - 1/10/97 Memorandum from the Director, Office of Device
Evaluation, Department of Health and Human Services, Subject:
Deciding When to Submit a 510(k) for a Change to an Existing
Device
754 - Regulatory Strategy Revision Log with 10/6/04 memo to
Scott Ciarrocca
755 - 2/8/05 Memo to Customer from Sean M. O'Bryan with
1/8/02 letter to Mr. Jones from Department of Health and Human
Services, Celia M. Witten, Ph.D., M.D.
756 - Gynecare ProLift IFU
757 - Gynecare Gynemesh PS IFU
758 - Gynecare Gynemesh PS IFU
759 - "Transvaginal mesh repair of anterior and posterior vaginal
wall prolapse: a clinical and ultrasonographic study," Velemir et
al.
760 - "Complications from vaginally placed mesh in pelvic
reconstructive surgery," Roberta Blandon, et al.
Sean M. O'Bryan - 06-06-13
T-471 - 2004 Performance and Development Plan Summary for
Sean O'Bryan
T-472 - Modified Gynecare TVT Obturator System Special
510(k)
T-473 - Email chain
T-474 - Email chain
T-475 - Email chain
T-476 - Email chain
T-477 - Email chain
T-478 - Email chain
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T-480 - Email chain T-481 - 8/14/03 email

ETH.MESH.00260526-	
ETH.MESH.00260527	T-483 - 8/27/03 Text Approval Form #2003-059 Rev 1
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ETH.MESH.00260475	T-484 - Email chain
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ETH.MESH.00865627	T-487 - 11/26/03 email
ETH.MESH.00866317-	1-407 - 11/20/03 email
ETH.MESH.00866318	T-488 - Email chain
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ETH.MESH.01810987-	1-403 - LIIIali Gialii
ETH.MESH.01810988	T-490 - Email chain
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ETH.MESH.00189089-	1-491 - 1/11/05 email
ETH.MESH.00189091	T-492 - 4/5/05 Minutes from Design Change Review
ETH.MESH.00261820-	1-492 - 4/3/03 Millutes Hoff Design Change Review
ETH.MESH.00261826	T-493 - TVT-O IFU
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ETH.MESH.06873458	Sean M. O'Bryan - 06-07-13  T-494 - 2/14/013 Due Diligence Growth Opportunity Outline
ETH.MESH.06873458 ETH.MESH.06873459-	T-494 - 2/14/013 Due Diligence Growth Opportunity Outline
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ETH.MESH.06873458 ETH.MESH.06873459- ETH.MESH.03926030- ETH.MESH.03926031 ETH.MESH.00260593- ETH.MESH.00260595 ETH.MESH.00260016- ETH.MESH.00260019 ETH.MESH.03934952- ETH.MESH.03934967 ETH.MESH.03910208- ETH.MESH.03910206 ETH.MESH.03910206 ETH.MESH.03918253- ETH.MESH.03918264	T-494 - 2/14/013 Due Diligence Growth Opportunity Outline T-495 - Email chain T-496 T-497 - Email chain T-498 - 10/7/02 Memo T-499 - 4/30/03 Meeting Report T-500 - 10/4/02 Report: Visit to Pr Jean de Leval T-501- 10/8/02 email

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ETH.MESH.00863841-	
ETH.MESH.00863842	T-505 - Matrix
ETH.MESH.00862729-	
ETH.MESH.00862732	T-506 - Email chain
ETH.MESH.00858092-	
ETH.MESH.00858093	T-507 - Gynecare R&D Monthly Update - June
ETH.MESH.00858175-	
ETH.MESH.00858177	T-508 - Mulberry Weekly Meeting Minutes for 6/3/03
ETH.MESH.00261584-	
ETH.MESH.00261585	T-509 - 6/9/03 email
ETH.MESH.02180737	T-510 - 6/24/03 email
ETH.MESH.03802343-	
ETH.MESH.03802345	T-511 - Mulberry Weekly Meeting Minutes for 6/24/03
ETH.MESH.01813074	T-512 - 4/18/03 email
ETH.MESH.00865127-	
ETH.MESH.00865128	T-513 - Email chain
ETH.MESH.01811862-	
ETH.MESH.01811863	T-514 - Email chain
ETH.MESH.01815607	T-515 - Email chain
ETH.MESH.01815621-	
ETH.MESH.01815623	T-516 - Email chain
ETH.MESH.01815722-	
ETH.MESH.01815723	T-517 - Email chain
ETH.MESH.03918752	T-518 - Email chain
ETH.MESH.03918791-	
ETH.MESH.03918792	T-519 - Email chain
ETH.MESH.06885495	T-520 - 10/17/03 email
ETH.MESH.00259303-	
ETH.MESH.00259315	T-521
ETH.MESH.06880472-	
ETH.MESH.06880478	T-522 - European Urology article
	T-523 - Code of Ethics for Regulatory Professionals
ETH.MESH.00865184-	<b>y y</b>
ETH.MESH.00865186	T-524 - Email chain
ETH.MESH.08450877-	
ETH.MESH.08450909	T-525 - Sean O'Bryan's personnel file
	T-526 - Sean O'Bryan's Resume
	Price St. Hilaire - 07-11-13
	T2063 - CV of Price St. Hilaire
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ETH.MESH.058158	About Stress Urinary Incontinence"
ETH.MESH.08003279-	T2075 - Gynecare TVT Family of Products brochure, "Treatment
ETH.MESH.08003294	Options for Stress Urinary Incontinence"
ETH.MESH.00160615-	T2076 - Gynecare Ethicon Brochure, "Freedom from Stress
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ETH.MESH.07946455-	
ETH.MESH.07946468	T2077 - ADM Module 2: Compliance
ETH.MESH.08003231-	T2078 - Brochure, "The Choice to End Stress Urinary
ETH.MESH.08003246	Incontinence"
ETH.MESH.00163558-	T2079 - Brochure, "The Choice to End Stress Urinary
ETH.MESH.00163574	Incontinence" - Bonnie Blair on cover
ETH.MESH.08003247-	T2080 - Brochure, "The Choice to End Stress Urinary
ETH.MESH.08003262	Incontinence" - Bonnie Blair on cover
ETH.MESH.03458123-	T2081- Brochure, "The Choice to End Stress Urinary
ETH.MESH.03458138	Incontinence" - Bonnie Blair on cover
ETH.MESH.00846523	T2082 - Email dated February 28, 2006
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	No. 1178 - Resume of Gene Kammerer
ETH.MESH.01220728-	
ETH.MESH.01220729	No. 1179 - Email string dated 2/13/04
ETH.MESH.01220730-	No. 1180 - Questions raised at follow-up meeting with Murty
ETH.MESH.01220731	Vykarnam and Mora Melican dated February 10, 2004

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ETH.MESH.00585687	No. 1186 - Email dated 5/19/06
ETH.MESH.00585688-	No. 1187 - Use of Ultrapro Mesh for Pelvic Organ Prolapse
ETH.MESH.00585690	(POP) Repair Through a Vaginal Approach
ETH.MESH.00585937-	
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ETH.MESH.01218424	the Prolift Experience
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	and conversations/interviews with
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ETH.MESH.03924586	surgeons
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ETH.MESH.01822361-	No. 3431 - E-mail chain, top one dated 18
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ETH.MESH.02340974-	
ETH.MESH.02340980	No. 3438 - Gynecare TVT Obturator System Instructions for Use
ETH.MESH.02340568-	No. 3439 - Gynecare TVT SECUR System
ETH.MESH.02340590	Instructions for Use
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ETH.MESH.09656790-	No. 1366 - 4/10 E-Mail Chain Among
ETH.MESH.09656791	Trzewik, Kvitle, Korseck, and Meier
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ETH.MESH.04123299	T-1306 - Email string, 4/22/10-4/28/10
	T-1307 - Document entitled "Trocar-guided mesh repair of
ETH.MESH.04123300-	vaginal prolapse using partially-absorbable mesh; one year
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ETH.MESH.04120969	T-1308 - Email string, 5/7/09-5/11/09
	T-1309 - Article entitled "Complication and Reoperation Rates
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	T-1313 - PowerPoint presentation entitled "Mesh Platform
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	T-1330 - Professional education program certificate for
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ETH.MESH.00994917-	T-1338 - Email, 4/13/05, to Amin and others from McCabe, with
ETH.MESH.00994918	attachment
ETH.MESH.08003263-	T-1339 - Brochure entitled "The Choice to End Stress Urinary
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	James C. Hart, M.D 12-20-13
	T-1340A - 2-page copy of document dated 3/22/10 entitled
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ETH.MESH.00408093	Form"
	T-1341A- 55-page copy of document dated 3/22/10 entitled "A
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ETH.MESH.03427878-	
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ETH.MESH.00220335-	T-1345A - 2-page copy of memo dated 12/2/99 to R. Rousseau
ETH.MESH.00220336	from Thomas A. Barbolt, Ph.D., D.A.B.T.
	T-1346A - 1-page copy of document dated 5/14/01 entitled
ETH.MESH.00220297	"Target Sheet"
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ETH.MESH.00658058-	T-1348A - 8-page copy of document entitled "The Leader in
ETH.MESH.00658065	Midurethral Sling Devices for the Treatment of SUI"
ETH.MESH.01186068-	T-1349A - 5-page copy of document entitled "Make Data and
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ETH.MESH.02237103-	T-1350A - 2-page copy of document entitled "Gynecare TVT
ETH.MESH.02237104	Family of Products Tension-free Support for Incontinence
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	Hart D-1 56-page copy of document entitled "Placeholder,"
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	Hart D. 2.0 nage capy of article dated 1/12 entitled "One Veer
	Hart D-2 9-page copy of article dated 1/12 entitled "One-Year Objective and Functional Outcomes of a Randomized
	Clinical Trial of Vaginal Mesh for Prolapse"
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ETIL MEQUI 0000074	T-1317 - Email, 4/26/11 to Savidge and others from Kanerviko
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	infection leading to squamous cell carcinoma of the abdominal
	wall"
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ETH.MESH.01192308	implants in urogynaecology" by Piet Hinou
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	T-681 - Article entitled "Anatomical variability in the trajectory of
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	Transcript Excerpt, September 9, 2011, 11 pp.
	T-717 - PowerPoint, "Lightning 9/6/08 Peter Meier," 22 pp.
	T-718 - Article entitled "Transvaginal mesh repair using a light-
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	prolapse using partially absorbable mesh: 1 year outcomes" by
	Alfredo L. Milani, MD, et al., 8 pp.
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	T-725 - Photograph of TVT Secur, 1 p.
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	T-728 - PowerPoint "Ethicon Women's Health and Urology
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	Plaintiff's-865
	T-363
	T-382
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	Plaintiff's-818
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	T-98a - Bryan A. Lisa Resume
ETH.MESH.07383028	T-99a - Regulatory is Exciting
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	T-115 - "Our Credo" J&J
	T-116 - Ethicon Code for the Conduct of R&D
	T-117 - Code of Ethics of Regulatory Professionals
ETH.MESH.08003089-	T-118 - Employee Secrecy, Noncompetition Nonsolicitation
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ETH.MESH.03665472-	T-144 - Bonnie Blair The Choice to End Stress Urinary
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ETH.MESH.03656727-	1-140 - Elliali Tillead
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ETH.MESH.06022108-	1-147 - Ellian Tineau
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E111.WEG11.00022100	T-149 - TVT Instructions 2009
ETH.MESH.01069790-	1 170 I V I IIIGU GOUOTIS 2000
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ETH.MESH.00071821-	T-152 - Gynecare TVT-Secur - Overview of 2007 Product
ETH.MESH.00071825	Complaints Involving MDR Serious Injuries
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	Plaintiff's-133 - Resume of Bryan A. Lisa, RAC, 2 pp.
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	Plaintiff's-158 - Agenda for Discussion of Al Letter for
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ETH.MESH.00126821-	Í
ETH.MESH.00126822	Plaintiff's-168 - E-mail dated 06 May 2008
ETH.MESH.00126755-	
ETH.MESH.00126757	Plaintiff's-169 - E-mail chain, top one dated 08 May 2008
ETH.MESH.00308747-	
ETH.MESH.00308891	Plaintiff's-170 - CE Mark Technical File for Prolift®
	Plaintiff's-171 - Document titled "FINAL - 10/21/08, FDA
	Notification About Use of Surgical Mesh to Treat Pelvic Organ
	Prolapse and Stress
ETH.MESH.00164023-	Urinary Incontinence Standby for Media/Analyst
ETH.MESH.00164025	Inquiries,"
ETH.MESH.00071794	Plaintiff's-172 - E-mail chain, top one dated 29 Jan 2009
HMESH_ETH_00457923 - HMESH_ETH_00457925	Frequently Asked Questions About The Release of New Construction PROLENE* polypropylene Mesh - Ethicon document answering internal FAQs about new construction PROLENE mesh, including why changes were made and how company will handle transition to new mesh
11WEST_ETT_00437323	company will handle transition to new mean
ETH.MESH.09267953 - ETH.MESH.09267960	RE: TVTO Dr. Feagins Case Follow Up - Emails discussing physician difficulties with TVT-O, variable difficulty of sheath removal with TVT-O, and a difficult TVT-O case of Dr. Feagins' and his concerns about leg pain and difficulty perforating the obturator foramen with TVT-O
ETH.MESH.00752208 - ETH.MESH.00752208	Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery - PowerPoint about use of meshes for pelvic floor surgery detailing mesh product requirements for surgical use and specific requirements for Sub-urethral slings and POP repairs
	RE: Value Proposition LIGHTning - Emails discussing the
	Lightning Mesh Project presentation and document outlining
ETH.MESH.03912425 -	Project Lightning's goals to reduce mesh erosion, folding,
ETH.MESH.03912428	crunching, shrinkage, and pain
	LIGHTning Project Initiation Proposal - Emailed proposal for
	Lightning project with stated objective to determine if existing
ETH.MESH.00870566 -	Ethicon mesh material can be improved to minimize
ETH.MESH.00870573	complication rates

	KEY FINDINGS FROM IUGA Interviews 2006 - Document listing
	key concerns and suggestions communicated by physicians and
ETH.MESH.01999561 -	summary of interviews with physicians about Ethicon's mesh
ETH.MESH.01999564	products
E111.MEG11.01333304	RE: Preclinical Contraction Model -Emails discussing mesh
	contraction and the possibility of pain cause by disturbance of a
HMESH_ETH_01801001 -	nerve, and emails debating about whether or not to continue that
HMESH ETH 01801004	
HIVESH_ETH_01801004	line of inquiry
	DE: Nonce irritation MAE. Empile discussing article about
	RE: Nerve irritation M4F - Emails discussing article about
UMESH STU 02257474	chronic pain associated with the placement of a mesh device,
HMESH_ETH_02357471 -	intrinsic interaction between nerves and mesh, and which
HMESH_ETH_02357476	studies should be done to research these topics further
LIMECUL ETIL 00000457	WG: Preclinical Information M4F- Emails discussing studies
HMESH_ETH_02322157 -	needed on possibility of interaction between mesh and facial
HMESH_ETH_02322158	nerve
ETIL MEQUI 04004040	Meeting Report - Report of meeting to discuss design
ETH.MESH.01961610 -	requirements for a next generation pelvic floor mesh called
ETH.MESH.01961611	Thunder
ETH.MESH.01818382 -	
ETH.MESH.01818397	
ETH.MESH.02590903 -	
ETH.MESH.02590904	An Investigational Study of Swine Models to Evaluate Mesh
ETH.MESH.25908742 -	Contraction and Tissue Integration Over a 13 Week Period -
ETH.MESH.02590781	Research report on a study of implanted PROLENE, PROLENE
ETH.MESH.02590878 -	Soft, and ULTRAPRO mesh in swine, including tables,
ETH.MESH.02590899	photographs, and a pathology report
	Thunder: Technical Review - Presentation on Thunder project to
	develop new mesh for pelvic floor repair, detailing need for new
ETH.MESH.02590865 -	mesh, technical requirements, marketing position, and research
ETH.MESH.02590865	activities
	RE: Ureter Obstruction - Prolift - Emails discussing complaints
	related to ureter obstruction or constriction and what kind of
ETH.MESH.00079680 -	changes should be made to the IFU for Prolift based on
ETH.MESH.00079683	complaints
	Indicates No C. Day I also also also Minutes from a 0000 monthing
	Minutes VoC Dr. Lobodasch - Minutes from a 2008 meeting
ETH.MESH.05901897 - ETH.MESH.05901897	about changes to Prolift material and procedure and questions about design

	MCA - Mesh for Contaminated Areas: Technical Summary-
	Emailed confidential report on developing mesh to work in vivo
	in contaminated areas of the body, and article by Andrew L.
	Lewis titled "Phosphoryl choline Technology" published in the
ETH.MESH.05845620 -	Encyclopedia of Biomaterials and Biomedical Engineering
ETH.MESH.05845643	(2004)
	Doug Hale's Article on Prolift - Email discussing article on Prolift
	and hyspareunia and the article, by Joyce K. Lowman, Leticia A.
	Jones, Patrick J. Woodman, and Douglass S. Hale, titled "Does
ETH.MESH.24107687 -	the Prolift System Cause Dyspareunia"? Published in the
ETH.MESH.24107693	American Journal of Obstetrics & Gynecology (Dec. 2008)
	Drolift Ultracound Email requesting correction of article on
	Prolift Ultrasound - Email requesting correction of article on ultrasonographic appearances following Prolift procedures,
	emailed comments from readers for the journal Ultrasound in
	Obstetrics and Gynecology, and attached article titled
ETH.MESH.02129838 -	"Transvaginal mesh repair of anterior and or posterior vaginal
ETH.MESH.02129859	wall prolapse: a clinical and ultrasonographic study"
E 111.WEG11.02 120000	The Goal of Lightweight Mesh - Notes discussing Gynemesh
	PS, Prolene, VYPRO, and ULTRAPRO mesh, differences
ETH.MESH.19976595 -	between lightweight and heavyweight mesh, and the rates of
ETH.MESH.19976599	complications occurring with each
	Project: T-PRO – Target product Profile 25 march 2009 -
	PowerPoint slide from presentation on T-PRO mesh project,
ETH.MESH.02141080 -	detailing efficacy, safety/tolerability, payer value, and indications
ETH.MESH.02141080	for T-PRO
	Discovery Project T-Pro - PowerPoint overview of T-Pro mesh
HMESH_ETH_02200921 -	project detailing material and constructions options, clinical
HMESH_ETH_02200921	requirements, test methods, challenges, and market opportunity
	June 16, 2000. Decument outbored by Dr. Debinson discussing
	June 16, 2009 - Document authored by Dr. Robinson discussing
	unique mesh characteristics that are necessary in pelvic organ reconstruction, the possible clinical impact of increased rigidity
ETH.MESH.12192215 -	with mesh, and statement that all future meshes will be less rigid
ETH.MESH.12192215	than Gynemesh PS
L 111.IVILO11. 12 1922 10	Educational Course # 16 Transvaginal Mesh Repair for Pelvic
	Organ Prolapse: Part II: Per and Post Operative Specific
	Complications - Document by B. Jacquetin and L. Velemir
ETH.MESH.00570726 -	discussing how to assess, prevent, and manage mesh
ETH.MESH.00570728	shrinkage.
	John Mago.

ETH.MESH.00086823 - ETH.MESH.00086829	Vaginal Mesh Contraction - Emails discussing article on contraction with Prolift titled "Vaginal Mesh Contraction Definition, Clinical Presentation, and Management" by B. Feiner, and C. Maher in Obstetrics & Gynecology (Feb. 2008) Vol 115, No 2
ETH.MESH.09928467 - ETH.MESH.09928527	Specific Complications After Transvaginal Mesh Repair with Kits: How to Prevent? How to manage? Workshop 30 - Schedule for workshop on mesh complications; presentations on mesh shrinkage, erosion, and sexual outcomes; document by B. Jacquetin discussing how to assess, manage, and prevent mesh shrinkage; document by P. Dwyer discussing recurrence of Pelvic Organ Prolapse after surgery
	Biomechanical Consideration for Pelvic Floor Mesh Design -
ETIL MEQUI 00040004	Report detailing technical development of design of next
ETH.MESH.02010834 -	generation pelvic floor mesh based on generating an advanced
ETH.MESH.02010855	understanding of pelvic floor biomechanics
ETI I ME OLI 00750045	Biomechanics (Pelvic Forces) - PowerPoint analyzing pelvic
ETH.MESH.03753245 -	forces for future mesh development and detailing technical
ETH.MESH.03753245	components of possible testing
ETIL MEOULOGAAGG	RE: French TVM 5-year and the Prolift Future - Emails
ETH.MESH.08313650 -	discussing the difficulties and future of TVM and Prolift, the
ETH.MESH.08313652	stance of IUGA, ACOG, and AUGS on mesh
ETH.MESH.000856903 (WITH	Team Latin Quarter PowerPoint 2007 - PowerPoint on TVT
NOTES)	Secur detailing procedure steps
ETIL MECIL 00056004	Secur Magic - Video advertising TVT Secur featuring a man
ETH.MESH.00856904	dressed as a magician
	New TVT-O IFU - from Ethicon Website (8 pp.)
	Module 3A: Mesh in Hernia Repair - In Search of the Optimal
	Mesh: The Impact of Alloplastic Mesh Material on Patient
	Outcome in Hernia Repair -PowerPoint detailing history of mesh,
HMESH ETH 00126243	host reaction to mesh and complications, and discussing optimal
	mesh design
	Balchandra DP, Landon C. Experienced surgeon equates low intraoperative complication rates after Prolift transvaginal mesh repair for pelvic organ prolapse. Abstract 777 at ICS 2014.

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ETH.MESH.07971048- ETH.MESH.07971055	Mesh Contraction Clinical - Email discussing article on mesh complications specific to Prolift, and stating these complications are the reason that Ethicon came out with Prolift +M, and article by B. Feiner and C. Maher titled "Vaginal Mesh Contraction: Definition, Clinical Presentation and Management"
ETH.MESH.13204508- ETH.MESH.13204521	RE: Product Complaint CC1007005- Taiwan - Emails discussing complaint about mesh pieces in unopened box of TVT-O, complaint form, and photographs
ETH.MESH.13206130- ETH.MESH.13206134	FW: Product Complaint CC1007047&CC1007048 - Taiwan - Emails requesting response from Ethicon on complaint of mesh pieces in unopened box of TVT-O and detailing additional instances of mesh pieces in TVT-O box.
ETH.MESH.01745568- ETH.MESH.01745572	RE: Product Complaint CC1007005- Taiwan - Emails discussing how to handle complaint about mesh pieces in unopened box of TVT-O and email recommending a meeting rather than an email chain
ETH.MESH.04101823- ETH.MESH.04101824 (+6 PP.)	Particles in TVTO Blisters - Emailed PowerPoint on complaints of foreign matter in TVTO blisters containing investigation of complaints and photographs
ETH.MESH.04101014- ETH.MESH.04101015	RE: 10100124625 etc Memo re TVT-O Particles - Emails discussing drafts of a memo responding to complaint about about mesh pieces in unopened box of TVT-O
ETH.MESH.00518699- ETH.MESH.00518702	Clinical Strategy for SECUR - Emails discussing potential studies with TVT-Secur, doctors concern that TVT-Secur is being launched without enough clinical data, and instructions not to communicate future clinical plans to Key Opinion Leaders Chmielowski, L., M.D., Walters, M., Webert, A., et al. "Reanalysis of Randomized Trial of 3 Techniques of Anterior Colporrhaphy Using Clinically Relevant Definitions of Success",
ETH.MESH.02090196- ETH.MESH.02090209	www.AJOG.org.  04/15/08-04/16/08 Trip Notes - Notes about Mini TVT-O cadaver surgery, discussions about TVT-O procedure and complications and differences between laser and mechanical cut mesh

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	MCA -Mesh for Contaminated Areas: Technical Summary -
ETH.MESH.05845620-	Emailed technical summary of search for MCA solutions for use
ETH.MESH.05845628	in contaminated areas
	Specific Complications after Transvaginal Mesh Repair with Kits
ETH.MESH.09928467-	Schedule of workshops on how to prevent and manage TVM
ETH.MESH.09928527	complications and PowerPoint presentation on these topics
	Shrinkage PowerPoint (54 pp.)
ETH.MESH.00838319-	Ethicon Prolift Physician IDI's - Report on qualitative research
ETH.MESH.00838352	conducted with physicians about Prolift
	AW: T-PRO - Emails discussing scope of clinical data needed to
ETH.MESH.00857704-	launch TPP, and TPPs advantages over Prolift +M in terms of
ETH.MESH.00857705	specific complications
	Prolift +M (Lightning) Background Information from R&D-
	PowerPoint detailing needed improvements to mesh, and project
	designed to determine if mesh material can be adapted for
ETH.MESH.05237875 (+11 pp.)	
	MCA -Mesh for Contaminated Areas: Technical Summary -
ETH.MESH.05845621-	Technical summary of search for MCA solutions for use in
ETH.MESH.05845627	contaminated areas
ETH.MESH.07237575- ETH.MESH.07237576	RE: Actually a Few More Questions - Emails discussing revision of response to statement that 'some surgeons prefer mesh without arms', which discusses potential for folding of the mesh, exposure of the arms, and resulting pain
	PP vs. PVDF/PRONOVA - Emails discussing alteration of
	polypropylene in the body, proposed new product developments
HMESH.ETH.00228961-	with more stable filaments, and management's decision to use
HMESH.ETH.00228973	polypropylene
ETH.MESH.09928467-70	
ETH.MESH.09928476	Specific Complications after Transvaginal Mesh Repair with Kits
ETH.MESH.09928500-	Schedule of workshops on how to prevent and manage TVM
ETH.MESH.09928520-	complications and PowerPoint presentation on these topics
	Equivalence Supported by Pre-clinical Performance Studies -
	Document summarizing anatomic study on the implant mesh's
ETH.MESH.08581280-	anatomic trajectory and a comparison study of initial implant
ETH.MESH.08581282	fixation force in a human cadaver

	I. E. I. C. IIIOVI (
	Key Findings from IUGA Interviews 2006 - Document listing key
ET.   14E0    0.400   0.4	concerns and suggestions communicated by physicians and
ETH.MESH.01999561-	summary of interviews with physicians about Ethicon's mesh
ETH.MESH.01999564	products
	AW: T-PRO - Emails discussing scope of clinical data needed to
ETH.MESH.00857704-	launch TPP, and TPPs advantages over Prolift +M in terms of
ETH.MESH.00857705	specific complications
	RE: 08005801 10100078154 - Emails discussing draft
	responses to Australian government's request to provide
ETH.MESH.04097128-	adverse event statistics for Prolift and response to allegation that
ETH.MESH.04097131	mesh migrated in patient's body
	Prolift +M (Lightning) Background Information from R&D -
	PowerPoint detailing needed improvements to mesh, and project
	designed to determine if mesh material can be adapted for
ETH.MESH.05237875 (79 pp.)	release of a new product
_ ::e:ee_e: e: e (: e pp:)	Product of a free product
	FW: Updated T-PRO Deck - Emailed PowerPoint on Project T-
ETH.MESH.02227282-	Pro detailing history of mesh, causes of mesh complications, T-
	Pro mesh design, and T-Pro rat study results
L111.WL311.02221203 (122 pp.)	1 10 mesh design, and 1-1 to fat study results
	DD va DVDE/DDONOVA Emails discussing alteration of
	PP vs. PVDF/PRONOVA - Emails discussing alteration of
	polypropylene in the body, proposed new product developments
	with more stable filaments, and management's decision to use
	polypropylene, and PowerPoint titled - WHU THUNDER
LIMECULETU 00000004	PRONOVA Characteristics and Prototype Screening in vivo,
HMESH.ETH_00228961-	discussing technical differences between PRONOVA and
HMESH.ETH_00228973	PROLENE and results of rat study
	Specific Complications After Transvaginal Mesh
	Repair with Kits: How to Prevent ? How to manage? Workshop
	30 - Schedule for workshop on mesh complications;
	presentations on mesh shrinkage, erosion, and sexual
	outcomes; document by B. Jacquetin discussing how to assess,
ETH.MESH.09928467-	manage, and prevent mesh shrinkage; document by P. Dwyer
ETH.MESH.09928527	discussing recurrence of Pelvic Organ Prolapse after surgery
	FW: Force and Pressure Justification - Emails discussing
	biomechanics of the pelvic floor and meshes and report titled
	Biomechanical Consideration for Pelvic Floor Mesh Design,
	detailing technical development of design of next generation
ETH.MESH.03753222-	pelvic floor mesh based on generating an advanced
ETH.MESH.03753246 (+ 4 pp.)	understanding of pelvic floor biomechanics
	and claiming of portro hoof promobilities

	RE: Actually a Few More Questions - Emails discussing revision
	of response to statement that 'some surgeons prefer mesh
ETH.MESH.07237575-	without arms', which discusses potential for folding of the mesh,
ETH.MESH.07237576	exposure of the arms, and resulting pain
	MCA -Mesh for Contaminated Areas: Technical Summary -
ETH.MESH.05845621-	Technical summary of search for MCA solutions for use in
ETH.MESH.05845627	contaminated areas
ETH.MESH.05454207-	
ETH.MESH.05454214	Photos Cadaver Lab - Emailed photo of mesh
	Prolene Microcracking - Report summarizing experimental
ETH.MESH.15958452-	findings relating to microcracking in explanted PROLENE
ETH.MESH.15958469	sutures, includes photos
	Prolene Microcrack Experiments - Report discussing additional
ETH.MESH.15958445-	data needed to interpret the in-vivo microcracking process and
ETH.MESH.15958451	outlining experiments designed to do so
	Gynemesh Vypro for Pelvic Floor Repair - Presentation on
ETH.MESH.12009633-	Gynemesh Vypro project detailing objectives, risk and market
ETH.MESH.12009657	assessment, launch strategy, and schedule
	Polyoxyester as a Tissue Engineering Material for Replacement
ETI I MESI I 06000873	of Muscle, Ligament, Fascia and other Tissue Types - Invention
ETH.MESH.06000873- ETH.MESH.06000875	disclosure draft and comments for material to replace surgical meshes which can cause erosions and painful adhesions
ETH.MESH.02270766-	RE: D'Art: Risk Question - Emails discussing concerns about
ETH.MESH.02270767	reports of mesh retraction/shrinkage
L111.WL311.02270707	TVT Tape - Letter of complaint from Dr. Eberhard re: crumbling
ETH.MESH.02180833	TVT tape - Letter of complaint from Dr. Ebernard re. crumbling
E111:WEG11:02100000	RE: Proposal for Work with CBAT - Emails discussing proposed
	study on synthetic and natural mesh and report from a
ETH.MESH.05574759-	conversation with a gynecologist on his requirements for an
ETH.MESH.05574761	ideal mesh
	Tacal Incom
	RE: ULTRAPOR vs PROLENE Soft Mesh - Emails discussing
	the replacement of PROLENE Soft mesh with UltraPro in
ETH.MESH.04020138-	Prolift/MINT and which attributes to investigate to show a
ETH.MESH.04020145	difference in the materials, such as reduced scar formation
	Minutes Hamburg Meeting June 2nd - Email containing the
ETH.MESH.00870465-	minutes from the Ethicon Expert Meeting on Meshes for Pelvic
ETH.MESH.00870476	Floor Repair

	Prospective TVM Studies - PowerPoint on TVM and Prolift
	studies in France and the U.S., failures and risk factors,
ETH MESH 00821702 (+25 pp.)	prospective studies, and outcomes
LTT.IWLST1.0002 17 02 (+23 pp.)	prospective studies, and outcomes
	An Investigational Study of Swine Medale to Evaluate Mech
	An Investigational Study of Swine Models to Evaluate Mesh
ETIL MEGIL 0404000	Contraction and Tissue Integration Over a 13 Week Period -
ETH.MESH.01818382-	Research report on a study of implanted PROLENE, PROLENE
ETH.MESH.01818397	Soft, and ULTRAPRO mesh in swine
ETH.MESH.03650906-	RE: Prolift +M Design Risk Documentation - Emails discussing
ETH.MESH.03650909 and	edits to risk documentation for Prolift +M and Prolift +M PFR
ETH.MESH.00513815-	Risk Management Report containing a review of complaints with
ETH.MESH.00513819	Prolift
	Thunder MGPP Decision Meeting PowerPoint - PowerPoint on
	Project Thunder detailing its potential role, value propositions,
ETH.MESH.02141727 (+22 pp.)	design options, and technical requirements
ETH.MESH.01202101-	RE: My Revised Write-up of the DeLeval and Waltregny Visit -
ETH.MESH.01202103	Emails discussing summary of a meeting on TVT-O
ETH.MESH.09650853-	Invention Disclosure - Draft of disclosure form for the invention
ETH.MESH.09650863	of an areal implant with body embedded properties
	Things to Consider as We Assess Next Steps for a Next
	Generation Sling- Emailed outline of discussions on possibilities
ETH.MESH.09951087-	of Professor DeLeval's Mini-me sling, a next generation TVT-
ETH.MESH.09951090	Secur, and a next generation Scion
	Promisa Take Away Messages - Email discussing summary of a
ETH.MESH.07171404-	meeting on Prosima PMP detailing differences between Prolift
ETH.MESH.07171406	and Prosima
	Biomechanics (Pelvic Forces) - PowerPoint analyzing pelvic
	forces for future mesh development and detailing technical
ETH.MESH.03753245 (44 pp.)	components of possible testing
	Today's vaginal implants do not consider the patient's
	biochemical needs (5 pp.)
	Mesh Properties - How Important are They? - PowerPoint by Dr.
	Meier about mesh complications, construction, and design
ETH.MESH.05237872 (+38 pp.)	•
ETH.MESH.08315779-	Clinical Expert Report on Prolift +M Pelvic Floor Repair System -
ETH.MESH.08315810	Report on Prolift +M
2.7.1.00010010	Troport on Fromt - W
ETH.MESH.01202101-	RE: My Revised Write-up of the DeLeval and Waltregny Visit -
ETH.MESH.01202101	Emails discussing summary of a meeting on TVT-O
L 11 1.1VILOI 1.0 1202 100	Linais discussing summary of a meeting on 1 v 1-0

	Implant Chart Chart detailing his competibility hasterial
ETIL MEGIL 05044040	Implant Chart - Chart detailing biocompatibility, bacterial
ETH.MESH.05644940-	adhesion, and general properties of PROLENE and PRONOVA
ETH.MESH.05644942	mesh
	PRONOVA Non-Absorbably Suture USP -Position Statement to
	Support Clinical Safety and Efficacy - Document discussing
ETH.MESH.08505072-	Ethicon's position that no clinical studies are required to
ETH.MESH.08505076	establish the clinical safety and efficacy of PRONOVA
	PRONOVA Mesh - Emailed article titled "Materials
ETH.MESH.05446082-	Characterization of Explanted Polypropylene Hernia Meshes" by
ETH.MESH.05446088	· · · · · · · · · · · · · · · · · · ·
ETH.WESH.03440000	C.R. Costello, S.L. Bachmann, B.J. Ramshaw, and S.A. Grant
	AW: PRONOVA Mesh - Emails discussing article on
	Polypropylene mesh and need for material improvement over
ETH.MESH.22482810	Polypropylene mesh
	PRONOVA Biomechanical Properties - Email discussing
	Thunder meeting and PRONOVA studies and presentation
ETH.MESH.14437803-	discussing a study titled PRONOVA vs. PROLENE: Surface
ETH.MESH.14437807	alterations of autoclaved meshes
	WHU THUNDER PRONOVA Characteristics and Prototype
	Screening in vivo - Presentation detailing the histology,
ETH.MESH.14422800 (+10 pp.)	biomechanics, and stability of PRONOVA
	MCA - Mesh for Contaminated Areas: Technical Summary-
	Emailed confidential report on developing mesh to work in vivo
	in contaminated areas of the body, and article by Andrew L.
	Lewis titled "Phosphoryl choline Technology" published in the
ETH.MESH.05845620-	Encyclopedia of Biomaterials and Biomedical Engineering
	l , , ,
ETH.MESH.05845643	(2004)
	AW: T-PRO - Emails discussing scope of clinical data needed to
ETH.MESH.00857704-	launch TPP, and TPPs advantages over Prolift +M in terms of
ETH.MESH.00857705	specific complications
	Re: Mesh + Anti-proliferative Agent - Emails discussing changes
	to reduce severity of scar formation and contracture and
ETH.MESH.03722384-	publications indicating that polypropylene produces an ongoing
ETH.MESH.03722386	chronic inflammatory reaction
	PP vs. PVDF/PRONOVA - Emails discussing alteration of
	polypropylene in the body, proposed new product developments
HMESH.ETH.00228961-	with more stable filaments, and management's decision to use
HMESH.ETH.00228973	polypropylene
	Boris Batke - 1/8/2013
ETH.MESH.05479501-	
ETH.MESH.05479502	T-1226-2 page document "Boris Batke"
L 111.IVILO11.0071300Z	1 1220 2 page document bons battle

ETH.MESH.05920616-	T-1227-2 page e-mail dated 7/20/07 to
ETH.MESH.05920617	Boris Batke, et al., from Martin Chomiak
	T-1228-1 page document entitled
	"Mesh/Devices"
ETH.MESH.01816988-	T-1229 1 page document entitled
ETH.MESH.01816990	"Placeholder," plus attachments
	T-1230-1 page document entitled "Document produced in native
ETH.MESH.0547953	format," plus attachment
ETH.MESH.05446127-	T-1231-2 page email dated 3/13/06 to
ETH.MESH.05446139	Dr. Dieter Engel, et al., from Dr. Joerg Holste, plus attachments
	T-1232-15 page article dated 2005 entitled
	"The lightweight and large porous mesh
	concept for hernia repair"
	T-1233-16 page document dated 3/11 entitled "Ethicon
	Polypropylene Mesh Technology"
ETH.MESH.05920530-	T-1234-1 page email dated 4/17/03 to Jill
ETH.MESH.05920532	Schiaparelli, et al., from Boris Batke
ETH.MESH.05920618-	
ETH.MESH.05920628	T-1235-4 page email dated 2/12/2008 to Gilliam Jamieson and
	Boris Batke from Petra Koehler, plus attachments
ETH.MESH.04015102-	T-1236-3 page email dated 3/1/12 to Casey
ETH.MESH.04015104	Mayes from Boris Batke
ETH.MESH.05585033-	T-1237-21 page document entitled
ETH.MESH.05585053	"Project Edelweiss,"
	T-1238-1 page document entitled
ETH.MESH.05916450	"Placeholder, "plus attachments
	T-1239-1 page document entitled
ETH.MESH.04037600	"Placeholder," plus attachments
	T-1240-1 page document entitled "Document
ETH.MESH.0547941	produced in native format,"
	T-1241-1 page copy of email dated 5/4/04 to
ETH.MESH.05918776	Karen Zaderej, et al., from Jill Schiaparelli
	Boris Batke - 2/8/2013
	T-1242-Disk entitled "The Benefits of
	Lightweight Meshes"
	T-1243-Jump drive
	T-1244-12 page document
	T-1245-2 page document dated 7/19/12
	entitled "English Translation," plus attachments
	· '
	T-1246-1 page article dated 6/1/10 entitled "What Can We Learn
	From Explanted Slings and Meshes in Pelvic Floor Surgery?"
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ETH.MESH.04036976-	
ETH.MESH.04036981	T-1247-6 page document dated 1/13/05 entitled "Report,"
ETH.MESH.00832555-	T-1248-2 page document entitled "Thunder Meeting Minutes
ETH.MESH.00832556	4.12.07,"
ETH.MESH.02219202-	T-1249-9 page document entitled "Material Specification for TVT
ETH.MESH.02219210	Prolene Polypropylene Mesh Roll Stock,"
	Christophe N.P. Vailhe - 6/20/2013
	T-1097-Curriculum vitae of Christophe N.P. Vailhe
	T-1098-Document entitled "Christophe Vailhe transferring to
ETH.MESH.07194129	Ethicon Women Health and Urology,"1/28/10
	T-1099-Document entitled "Polypropylene Mesh for Pelvic Floor
	Repair (PFR), Focus on Mesh Exposure, Road to
ETH.MESH.03719177-95	Improvement,"10/14/11
ETH.MESH.00584846-47	T-1100-Email string, 5/10/04
ETH.MESH.03160750-52	T-1101-Email string, 11/13/06-11/15/06
	T-1102-Document entitled "Ethicon Expert Meeting, Meshes for
ETH.MESH.00870466-76	Pelvic Floor Repair," 6/2/06
	T-1103-Email, 1/29/12, to Batke and others from Landgrebe,
ETH.MESH.04038031-55	with attachments,
ETH.MESH.03031629-31	T-1104-Email string, 2/23/11
ETH.MESH.00584561	T-1105-Email, 10/21/10, to Vailhe from Krammerer
ETH.MESH.02227221-22	T-1106-Email, 4/8/08, to Meier and others from Holste
	T-1107-Email, 9/9/09, to Meek and others from Meier, with
ETH.MESH.02157878-80	attachment
	Christophe N.P. Vailhe - 6/21/2013
ETH.MESH.08579092-93	T-1108-Email, 1/9/12, to Volpe and others from Vailhe
ETH.MESH.07200381	T-1109-Email, 2/1/12, to Volpe from Vailhe
	T-1110-Powerpoint entitled "Mesh Exposure Ethicon Position,
ETH.MESH.07200382	February 2, 2012,"
ETH.MESH.04548236-42	T-1111-Document entitled "CDMA Meeting Minutes - 2012,"
	T-1112-Letter, 11/1/10, to Richter from Berman and Robinson,
ETH.MESH.07192033-41	with attachments
ETH.MESH.07192242	T-1113 Email, 2/17/11, to Bird and others from Meier
	T-1114-PowerPoint entitled "Investigation in Mesh Erosion in
ETH.MESH.02589032-79	Pelvic Floor Repair," 5/18/11
ETH.MESH.07198825-28	T-1115-Email string, 5/18/11-7/21/11
	T-1116-PowerPoint entitled "Investigating Mesh Erosion in
ETH.MESH.07192929	Pelvic Floor Repair,"
	T-1117-Document entitled "PA Consulting Group, Mesh Erosion
ETH.MESH.07192012-14	Interview - Surgeon," Minutes of Meeting, 1/20/11
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ETIL MEOLL 07400440 44	T-1118-Document entitled "PA Consulting Group, Mesh Erosion
ETH.MESH.07192412-14	Interview - Pathology," Minutes of Meeting 1/18/11
ET. 1.07450.50	T-1119-Document entitled "Clinical Expert Report, Gynecare
ETH-07152-58	Prolift Pelvic Floor Repair System," 1/14/15
ETH.MESH.07197998	T-1120-Email, 2/9/11, to Richter and others from Vailhe
ETH.MESH.07192872-77	T-1121-Email string, 4/11/11-5/18/11, with attachment
	T-1122-Document entitled "Biochemical consideration for Pelvic
ETH.MESH.02185584-605	floor mesh design," 2/16/11
ETH.MESH.07200224-44	T-1123-Email, 1/16/12, to Trzewik from Vailhe, with attachment
	T-1124-Article entitled "Anterior Colporrhaphy versus
	Transvaginal Mesh for Pelvic-Organ Prolapse," The New
	England Journal of Medicine
	Joerg Holste - 7/29/2013
	T-1192-1 page document entitled "Meshes/Devices"
	T-1193-1 page document entitled "Material"
ETH.MESH.01816988-	T-1194 - 1 page document entitled "Placeholder," plus
ETH.MESH.01816990	attachments
	T-1195-2 page letter dated 1/28/98 to Mr. Gregory R. Jones
	from Celia M. Witten, Ph.D., M.D., plus attachment
ETH.MESH.02219202-	T-1196-9 page copy of document entitled "Material Specification
ETH.MESH.02219210	for TVT Prolene Polypropylene Mesh Roll Stock,"
ETH.MESH.09479067-	T-1197-1 page copy of document entitled "TVT Prolene
ETH.MESH.09479068	Polypropylene Mesh Roll Stock, Appendix II, plus attachment
ETH.MESH.03146492-	T-1198-2 page copy of email dated 2/16/11 to Judi Gauld, et al.,
ETH.MESH.03146516	from Dr. Joerg Holste, plus attachments
ETH.MESH.02148431-	T-1199 -2 page copy of email dated 4/22/09 to Jonathan Meek,
ETH.MESH.02148460	et al., from Dr. Joerg Holste, plus attachments
	T-1200-7 page article dated 2005 entitled "The Argument for
	Lightweight Polypropylene Mesh in Hernia Repair
	T-1201-15 page article dated 2005 entitled "The lightweight and
	large porous mesh concept for hernia repair"
ETH.MESH.05446127-	T-1202-2 page email dated 3/13/2006 to Dr. Dieter Engel, et al.,
ETH.MESH.05446139	from Dr. Joerg Holste
	T-1203-1 page document entitled "Placeholder," plus
ETH.MESH.00838428	attachments
	T-1204-1 page document entitled "Document produced in native
ETH.MESH.05483362	format," plus attachments
	,

ETH.MESH.08315779-	T-1205-32 page document dated 9/24/12 entitled "Clinical
ETH.MESH.08315810	Expert Report,"
ETH.MESH.00659678-	T-1206-13 page article dated 11/04 entitled "Journal De
ETH.MESH.00659690	Gynecologie Obstetrique,"
	T-1207-4 page document entitled "Document produced in native
ETH.MESH.05718952	format,"
	Joerg Holste - 7/30/2013
ETH.MESH.05549189-	T-1208-3 page email dated 3/11/05 to Sandy Savidge, et al.,
ETH.MESH.05549191	from Dr. Joerg Holste
ETH.MESH.05505944-	T-1209-3 page document entitled "Clinical Infection Risk
ETH.MESH.05505946	Assessment for Gynecare TVT Universal (TVT U),"
	T-1210-1 page document dated 4/08 entitled "Interim report
ETH.MESH.00006636	mesh explants pelvic floor repair,"
ETH.MESH.02157879-	T-1211-2 page document entitled "Intermediate Report -
ETH.MESH.02157880	Prolapse Mesh Explants 6/2009,"
	T-1212-2 page document dated 5/6/13 entitled
	"Infections/Inflammation of the Genitourinary Tract: Kidney &
	Bladder (I)"
	T-1213-5 page article dated 2/2/06 entitled "In vitro infectability
	of prosthetic mesh by methicillin-resistant Staphylococcus
	aureus"
	T-1214-7 page copy of article dated 9/2/09 entitled "Bacterial
	colonization of collagen-coated polypropylene vaginal mesh: are
	additional intraoperative sterility procedures useful?"
	T-1215-5 page article dated 4/21/06 entitled "A 3-month
	preclinical trial to assess the performance of a new TVT-like
	mesh (TVTx) in a sheep model"
ETH.MESH.05245392-	T-1216-8 page email dated 12/21/04 to Steve Bell, et al., from
ETH.MESH.05245399	Dr. Joerg Holste
ETH.MESH.06403724-	
ETH.MESH.06403740	T-1217-17 page document entitled "3-Month Sheep Study,"
ETH.MESH.05246116-	T-1218-7 page email dated 1/3/06 to Allison London Brown, et
ETH.MESH.05246122	al., from Dan Smith
L 111.WLO11.03240122	T-1219-1 page document entitled "Placeholder Document
ETH.MESH.00840056	produced in native format,"
L 111.WLS11.00040030	produced in native ionnat,
ETH.MESH.04939027-	T 1220 0 page document dated 2/28/06 entitled "Corporate
	T-1220-9 page document dated 2/28/06 entitled "Corporate
ETH.MESH.04939035	Product Characterization Plan for Gynecare TVT S (Secur),"
ETH.MESH.00019925-	T-1221-2 page letter dated 11/26/05 to Patricia M. Hojnoski,
ETH.MESH.000120019	M.S., from Mark N. Melkerson, plus attachments
	T-1222-8 page article entitled "Hernia Repair Sequelae"

	T-1223-6 page article dated 3/19/06 entitled "Tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for stress urinary incontinence: A multicenter randomized trial"
	T-1224-1 page memo dated 7/16/10 to Leslie Young from Joerg
ETH.MESH.04940233	L. Holste, DVM, Ph.D., and Larry Johnson, DVM, Ph.D.,
ETH.MESH.05127423-	T-1225-2 page email dated 1/20/10 to Petra Koehler, et al., from
ETH.MESH.05127430	Dr. Joerg Holste, plus attachments
	Aaron Kirkemo 7/7/2014
ETH.MESH.01252509-	
ETH.MESH.01252512	T-3461-12/09 and 5/10 E-Mail Chain
ETH.MESH.08581412-	
ETH.MESH.08581413	T-3462-2/7/10 and 2/8/10 E-Mail Chain
ETH.MESH.06927231-	
ETH.MESH.06927235	T-3463-3/9/10 E-Mail Chain
	T-3464T-5/18/10 Power Point "Gynecare TVT Abbrevo Launch
	Planning
ETH.MESH.03753682	Stage Gate PLT,"
211231331 3332	T-3465-3/25/10 Power Point "Gynecare TVT Abbrevo Launch
ETH.MESH.00632511	Planning Stage Gate EWHU Board,"
ETH.MESH.01239065-	r tallining stage sate Errite Beara,
ETH.MESH.01239066	T-3466-7/16/09 E-Mail Chain
ETH.MESH.00592915-	TO TOO THE TOO IN THE
ETH.MESH.00592916	T-3467-9/11/09 E-Mail Chain
ETH.MESH.02340902-	
ETH.MESH.02340908	T-3468-TVT-O Instructions for Use
ETH.MESH.02341203-	To receive the amountaine for each
ETH.MESH.02341213	T-3469-TVT Abbrevo Instructions for Use
ETH.MESH.00209295-	TO TOO TO TO TABLETO MONIGORO TO TOO
ETH.MESH.00209299	T-3470-9/09 E-Mail Chain
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ETH.MESH.06005207-	T-3471-"The perils of commercially driven surgical innovation"
ETH.MESH.06005210	Article
ETH.MESH.00595406-	7 truoic
ETH.MESH.00595407	T-3472-1/4/10 E-Mail from Kirkemo to Gauld, et al,
ETH.MESH.05809872-	1 0-1/2 1/-/ 10 E Mail Holli Milkellio to Cadia, et al,
ETH.MESH.05809872	T-3473-"The TVT Worldwide Observational Registry" Study,
ETH.MESH.0503677	TOTAL THE TVT WORLDWIGE OBSERVATIONAL INEGISTRY OLDUY,
ETH.MESH.05135901	T-3474-4/10 and 5/10 E-Mail Chain
ETH.MESH.02842658-	1-0-7-7-7-10 and 3/10 E-iviali Orialii
ETH.MESH.02842659	T-3475-6/15/10 TVT-World Monthly Meeting Minutes
L 111.WLOI1.02042008	11-0-10-10-10-10-1-vir-vvolid iviolitility ivicetility iviilidies

ETH.MESH.00597472-	
ETH.MESH.00597477	T-3476-1/4/11 E-Mail from Tincello to Urquhart, et al,
E111.WEG11.00337477	Previously Marked Exhibits:
	T-239 Page 456
	T-499 Page 461
	Daniel J. Lamont - 9/11/2013
ETH. MESH.01813975-	Darner G. Edinorit 3/11/2010
ETH. MESH.01813978	T-3160-E-mail string
2111. M2611.01010010	T-3161-PowerPoint presentation entitled "LCM Project,
	Photographs Comparing Laser
ETH.MESH.08334245	Cut Mesh vs Mechanical Cut
ETH.MESH.00526473-	Cat Moon to Moonamoar Gat
ETH.MESH.00526474	T-3162-E-mail, 5/6/05, to Leclair and others from London Brown
ETH.MESH.01822361-	1 5 1 5 2 2 main, 6/6/66, to 250iain and 5there from 251ath 516th.
ETH.MESH.01822363	T-3163-E-mail string, 10/18/06
ETH.MESH.00687819-	3, 1 1 1
ETH.MESH.00687822	T-3164-E-mail string, 5/23/05-12/19/05
ETH.MESH.06881079-	3,
ETH.MESH.06881080	T-3165-E-mail string, 2/27/04
ETH.MESH.00439996-	3.
ETH.MESH.00439999	T-3166-E-mail string, 12/17/04-1/5/05
ETH.MESH.06924641-	T-3167-Memorandum, 9/1/10, to DHF0000978-TOPA from
ETH.MESH.06924643	Briceno and Kirkemo,
	T-3168-Resume of Daniel Lamont
ETH.MESH.07276458-	
ETH.MESH.07276459	T-3169-Notice of FDA Action, 7/9/12
	T-3170-MHRA Medical device adverse incident report form - for
ETH.MESH.07268127	members of the public
ETH.MESH.06773538-	
ETH.MESH.06773542	T-3171-E-mail string,11/22/11-7/4/12
ETH.MESH.06773543	T-3172-MHRA Adverse Incident Report, 7/5/10,
ETH.MESH.06773520-	
ETH.MESH.06773524	T-3173-E-mail string, 5/11/12-10/22/12,
ETH.MESH.00302390-	
ETH.MESH.00302392	T-3174-Memo, 2/23/06, to DHF0000176 from Lamont
	T-3175-Document entitled "Design
ETH.MESH.01218019	FMEA TVT LCM Project,
ETH.MESH.01068905-	
ETH.MESH.01068906	T-3176-E-mail string, 9/1/10-9/9/10
	Martin Weisberg - 5/30/2013
	T-311-Curriculum Vitae
ETH.MESH.03801821-	
ETH.MESH.03801822	T-312-E-mail dated 05 Dec 2002

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ETH.MESH.03918324	T-313-E-mail dated 05 Dec 2002,
ETH.MESH.03918325-	T-314-E-mail chain, top one dated 05 Dec
ETH.MESH.03918326	2002
ETH.MESH.03918327-	T-315-E-mail chain, top one dated 05 Dec
ETH.MESH.03918328	2002
ETH.MESH.03918329-	T-316 E-mail chain, top one dated 05 Dec
ETH.MESH.03918331	2002
ETH.MESH.03918332-	T-317-E-mail chain, top one dated 05 Dec
ETH.MESH.03918334	2002
ETH.MESH.03918335-	
ETH.MESH.03918337	T-318-E-mail chain, top one dated 06 Dec 2002
ETH.MESH.01815660-	T-319-Project Mulberry Preliminary
ETH.MESH.01815664	Clinical Diligence Report, 2003-01-06
ETH.MESH.03934876-	T-320-E-mail chain, top one dated 25 Mar
ETH.MESH.03934879	2003
ETH.MESH.00865216-	T-321-E-mail chain, top one dated 08 Apr
ETH.MESH.00865217	2003
ETH.MESH.00865220-	T-322-E-mail chain, top one dated 08 Apr
ETH.MESH.00865221	2003
ETH.MESH.00858080-	
ETH.MESH.00858081	T-323-Typewritten Follow-ups
ETH.MESH.00260591-	
ETH.MESH.00260592	T-324-E-mail chain, top one dated 14 Apr 2003
	T-325-E-mail chain, top one dated 16 Apr
ETH.MESH.03918497	2003
ETH.MESH.00865069-	
ETH.MESH.00865072	T-326-E-mail dated 16 Apr 2003
ETH.MESH.03801837	T-327-E-mail dated 20 Apr 2003
ETH.MESH.03801838-	
ETH.MESH.03801846	T-328-Draft Clinical Opinion
ETH.MESH.03934952-	T-329-Tension-free Vaginal Obturator Tape (TVOT) - April 30
ETH.MESH.03934967	2003 - Meeting report
ETH.MESH.00262089-	T-330-Editorial Manager (tm) for European Urology Manuscript
ETH.MESH.00262123	Draft
	T-331 Article entitled "Novel Surgical Technique for the
	Treatment of
	Female Stress Urinary Incontinence:
ETH.MESH.00259646-	Transobturator Vaginal Tape
ETH.MESH.00259652	Inside-Out" by Jean de Leval,
ETH.MESH.03935061	T-332-E-mail dated 19 Jun 2003
ETH.MESH.01815567-	
ETH.MESH.01815568	T-333-E-mail chain, top one dated 19 Jun 2003
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	T-334-E-mail chain, top one dated 24 Jun
ETH.MESH.01815607	2003
ETH.MESH.03928540-	2003
ETH.MESH.03928542	T-335-E-mail chain, top one dated 17 Jul 2003
ETH.MESH.00259634-	1-333-E-mail chain, top one dated 17 3di 2003
ETH.MESH.00259644	T-336-Clinical Expert Report
ETH.MESH.02340829-	1-330-Gillical Expert Neport
ETH.MESH.02340829-	T-337-Gynecare TVT Obturator System IFU
ETH.MESH.03589125-	1 007 Cynicoare 1 v 1 Obtarator Cystem ii C
ETH.MESH.03589126	T-339-MedWatch form, Mfr report #2210968-2004-00289
ETH.MESH.00261557-	T-340-E-mail chain, top one dated 10 Jul
ETH.MESH.00261558	2003
ETH.MESH.03803462-	
ETH.MESH.03803465	T-341-E-mail chain, top one dated 08 Aug 2003
ETH.MESH.01808684-	1 0 1 1 2 man onam, top one dated 50 7 tag 2000
ETH.MESH.01808686	T-342-E-mail chain, top one dated 19 Dec 2003
	Martin Weisberg 5/31/2013
ETH.MESH.03737968-	T-343-Clinical Expert Report: GYNEMESH
ETH.MESH.03737975	PROLENE Soft (Polypropylene) Mesh
ETH.MESH.03736578	T-344-E-mail dated August 28, 2000
ETH.MESH.04385229-	1 0 1 1 E mail dated / tagdet 20, 2000
ETH.MESH.04385245	T-345-Clinical Expert Report GYNECARE TVT SECUR System
ETH.MESH.08183517-	1 0 10 0 miliodi Export Roport O 11120/ it C 1 1 1 0 2 0 0 1 C yotom
ETH.MESH.08183520	T-346-Application for Employment of Martin Weisberg
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